

UNITED SAFETY AGENTS
F S V P
COMPLIANCE PLAN

TUFF BEAR, LLC

Name of FSVP Importer

BEE'S INN MANUKA LTD. – SAMUEL & CHRISTINE WEST

Name of Foreign Supplier

NEW ZEALAND REWAREWA HONEY AND MANUKA HONEY (UMF 5+, 10+, 15+, AND 20+)

Name of Product

APRIL 13, 2019 / APRIL 17, 2021

Date of Initial Verification / Reverification

APRIL 18, 2022

Date of FSVP Plan Expiration

VERIFICATION COMPLETE | PRODUCTS APPROVED FOR IMPORT

Status of Review

NUMBER 03

Version



– Confidential –



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OVERVIEW of FSVP PLAN

Title 21 of the Code of Federal Regulations requires that “... for each food you import; you must develop, maintain, and follow an FSVP that provides adequate assurances that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the Federal Food, Drug, and Cosmetic Act. . .” for each product (and each foreign supplier of each product) that our client imports, United Safety Agents (USA) has been engaged to undertake and successfully complete all requisite actions on our client’s behalf. USA has leveraged our 95 years of combined food-safety and FDA-regulatory experience to analyze, verify, build and maintain this FSVP plan that our client will now use to keep in compliance with the FDA’s FSVP regulations.

INSTRUCTIONS

Please review this FSVP plan in its entirety and sign where indicated. 21 C.F.R., §1.510 requires that this FSVP plan be kept on file for a minimum of two years after their use is discontinued. All records must be legible and stored to prevent deterioration or loss. If requested in writing by the FDA, you must send records to the Agency electronically, or through another means that delivers the records promptly. Offsite storage of records, including records maintained by other entities in accordance with §1.504, §1.505, or §1.506, is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location. Records obtained by the FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter. **Please contact United Safety Agents immediately to report a change in a foreign supplier’s process or status**, in the case of an FDA inspection, or with any questions that you may have via email at info@unitedsafetyagents.com, via fax at +1 888 557 2649, or via phone at +1 888 551 7403.

TERMS & DEFINITIONS

FSVP Importer (Importer). The importer is the U.S. owner or consignee of an article of food that is being offered for import into the United States. **U.S. owner or consignee** means the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

Foreign Supplier (Supplier). The foreign supplier or supplier is the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States.

Qualified Individual (QI). Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under this subpart.

Verified & Approved. Verified & approved means only that actions were taken to fulfill regulatory obligations. It does NOT mean that the product(s) listed in this FSVP plan is/are safe to consume or ready for human consumption.

RULES of USE

This FSVP plan is considered proprietary, privileged and confidential. It may not be reproduced in whole, or part, nor may it be shared with any third party – including a customer – without the prior written consent of United Safety Agents. All FSVP plans are bound under the terms of the Agreement which has been made between your company and United Safety Agents. Please see <https://www.unitedsafetyagents.com/rulesofuse> for more information.

FOREIGN SUPPLIER VERIFICATION PROCEDURES

21 C.F.R., §1.506 (a), (a)(2), (b), and (c) require that written procedures are established and followed to ensure that food is imported from approved suppliers only and that these procedures provide adequate assurance that the hazards requiring a control in the imported food have been significantly minimized or prevented. 21 C.F.R., §1.506 (d) requires that “... Except as provided in paragraphs (d)(2) and (3) of this section, before importing a food from a foreign supplier, [an FSVP Importer] must determine and document which verification activity or activities listed in paragraphs (d)(1)(ii)(A) through (D) of this section, as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the food [an FSVP Importer] obtain[s] from the foreign supplier is produced in accordance with paragraph (c) of this section. Verification activities must address the entity or entities that are significantly minimizing or preventing the hazards or verifying that the hazards have been significantly minimized or prevented (e.g., when an entity other than the grower of produce subject to part 112 of this chapter harvests or packs the produce and significantly minimizes or prevents the hazard or verifies that the hazard has been significantly minimized or prevented, or when the foreign supplier's raw material supplier significantly minimizes or prevents a hazard). The determination of appropriate supplier verification activities must be based on the evaluation of the food and foreign supplier conducted under §1.505.” As an FSVP Agent or Qualified Individual, USA's FDA-mandated goal is to verify that a product's innate physical, chemical and biological hazards are being controlled in a manner that is at least equivalent to the FDA's domestic standards. In order to accomplish this goal, documentation of a foreign supplier's processes, procedures and control methods will be required. Understanding that all foods may not share identical hazards - their control(s) also not being identical - USA utilizes a variety of foreign supplier verification activities to verify that a food's hazards have been significantly minimized or prevented. USA's determination of appropriate supplier verification activities is based on an evaluation of a specific food, its relevant hazards, and its corresponding foreign supplier. The following activities may be used to satisfy the requirements of 21 C.F.R., §1.506 (a), (a)(2), (b), (c), and (d):



A foreign supplier's Hazard Analysis and Critical Control Point (HACCP) plan may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's HACCP plan will be included within this FSVP plan.



An onsite audit of a foreign supplier's facility may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's onsite audit report will be included within this FSVP plan.



Sampling and testing of a food may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's reviewed sampling and testing results will be included within this FSVP plan.



A foreign supplier's relevant food safety record(s) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's relevant food safety record(s) will be included within this FSVP plan.

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FOREIGN SUPPLIER VERIFICATION PROCEDURES

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Certifying documents for a foreign supplier's Qualified Individual(s) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the certifying documents for a foreign supplier's Qualified Individual(s) will be included within this FSVP plan.



A food's nutritional label(ing) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the food's nutritional label(ing) will be included within this FSVP plan.



Completion of the FSVP Importer's Supplier Assessment Questionnaire and/or the FSVP Importer's Allergen and Intolerance Questionnaire may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the completed Questionnaire(s) will be included within this FSVP plan.



Documentation that a foreign supplier is in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and that the food is within the scope of that official recognition or equivalency determination, and that the foreign supplier of the food is in good compliance standing with the food safety authority of the country in which the foreign supplier is located may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of all substantiating documents will be included within this FSVP plan.



Documentation that a foreign supplier meets the definition of a qualified facility (as defined by §117.3 or §507.3) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of all substantiating documents will be included within this FSVP plan.



The FSVP Importer may rely upon performance of activities by other entities. If the FSVP Importer relies upon supplier verification activities conducted by another entity, the FSVP Importer will review and assess the results of these activities. Notation and documentation of the FSVP Importer's review and assessment will be recorded in this FSVP plan, including documenting that the determination of appropriate verification activities was made by a Qualified Individual.



When the FSVP Importer determines that a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the FSVP Importer will require a copy of the foreign supplier's annual onsite audit results. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's annual onsite audit results will be included within this FSVP plan. After initial verification, the FSVP Importer will require that the foreign supplier provide copies of their annual onsite results at least annually thereafter.

Continued onto next page.

FOREIGN SUPPLIER VERIFICATION PROCEDURES

Continued from previous page.



It may be required that the FSVP Importer conduct or obtain documentation of other (not previously mentioned) appropriate supplier verification activity(s) based on the foreign supplier's performance and the risk associated with the food. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the supplier verification activity(s) will be included within this FSVP plan.

FREQUENCY of VERIFICATION PROCEDURES

All above noted foreign supplier verification procedures and activities will be conducted and/or re-conducted at a frequency appropriate to the relevant procedure/activity and the corresponding hazard profile for the relevant food. Please refer to document-specific notes found on pg. 11, Ongoing Document Requirements found on pg. 12, Additional Recommendations found on pg. 21, and Verification Timeline found on pg. 23 for information about the frequency of verification procedures.

USE of APPROVED SUPPLIERS ONLY

Food and/or food-related products should only be imported from foreign suppliers that have been verified to the standards of FSVP. Prior to importation, all steps necessary to successfully verify that a foreign supplier's food safety processes and procedures meet the requirements of FSVP (*and other applicable regulations*), must be undertaken. Once complete, the product specific FSVP plan - created by United Safety Agents - will denote a supplier's status on the Title Page of each plan. Importation may occur if the following three parameters are met: 1) the FSVP plan's status does not read "Denied" or other wording denoting that product is not currently approved for import; 2) the date of importation will fall within one calendar year (*365 days*) from the plan's noted "Review End" date, and 3) there are no outstanding issues or changes in the supplier's processes and/or procedures since the noted "Review End" date.

CORRECTIVE ACTIONS

The FSVP Importer will take prompt corrective actions if it determines that a foreign supplier does not produce food consistent with the written assurance, and in compliance with applicable processes and procedures that provide same level of protection as FDA requirements. If the FSVP Importer determines by means other than verification activities that a foreign supplier does not produce food in compliance with applicable processes and procedures that provide the same level of protection as FDA requirements, it will conduct an investigation to determine whether the FSVP should be modified accordingly. Such corrective actions are dependent upon the specific circumstances of the deviation but could include: the complete discontinued use of the foreign supplier, or the discontinued use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed.

IDENTIFICATION of FSVP IMPORTER

The FSVP Importer will ensure that, for each line entry, the following information is provided to U.S. Customs and Border Protection: 01) FSVP Importer's Business Name; 02) FSVP Importer's Electronic Mail Address; and 03) The FSVP Importer's FDA acceptable UFI (*Unique Facility Identifier*) such as a DUNS number.

Supplier: Bee's Inn

Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI Member, USA LLC)

Review Start: April 02, 2021 Review End: April 17, 2021

UNITED STATES CODE of FEDERAL REGULATIONS

The following are or may be applicable to this product/supplier, FSVP Importer should confirm & comply independently.

- ▣ **101.** §101.1–101.108. Food Labeling.
- ▣ **106.** §106.1–106.160. Infant Formula Requirements
Pertaining to Current Good Manufacturing
Practice, Quality Control Procedures, Quality
Factors, Records and Reports, & Notifications.
- ▣ **110.** §110.3–110.110. Current Good Manufacturing
Practice in Manufacturing, Packing, or Holding
Human Food.
- ▣ **111.** §111.1–111.610. Current Good Manufacturing
Practice in Manufacturing, Packaging, Labeling,
or Holding Operations for Dietary Supplements.
- ▣ **112.** §112.1–112.213. Standards for the Growing,
Harvesting, Packing, and Holding of Produce for
Human Consumption.
- ▣ **113.** §113.3–113.100. Thermally Processed Low-Acid
Foods Pkged in Hermetically Sealed Containers.
- ▣ **114.** §114.3–114.100. Acidified Foods.
- ▣ **117.** §117.1–117.475. Current Good Manufacturing
Practice, Hazard Analysis, and Risk-Based
Preventive Controls for Human Food.
- ▣ **120.** §120.1–120.25. Hazard Analysis and Critical
Control Point (HACCP) Systems.
- ▣ **121.** §121.1–121.401. Mitigation Strategies to Protect
Food Against Intentional Adulteration.
- ▣ **123.** §123.3–123.28. Fish and Fishery Products.
- ▣ **129.** §129.1–129.80. Processing/Bottle Drinking Water.
- ▣ **131.** §131.3–131.206. Milk and Cream.
- ▣ **133.** §133.3–133.196. Cheeses & Related Products.
- ▣ **135.** §135.3–135.160. Frozen Desserts.
- ▣ **136.** §136.3–136.180. Bakery Products.
- ▣ **137.** §137.105–137.350. Cereal Flours.
- ▣ **139.** §139.110–139.180. Macaroni & Noodle Products.
- ▣ **145.** §145.3–145.190. Canned Fruits.
- ▣ **146.** §146.3–146.187. Canned Fruit Juices.
- ▣ **150.** §150.110–150.160. Fruit Butters, Jellies,
Preserves, and Related Products.
- ▣ **152.** §152.126. Fruit Pies.
- ▣ **155.** §155.3–155.201. Canned Vegetables.
- ▣ **156.** §156.3–156.145. Vegetable Juices.
- ▣ **158.** §158.3–158.170. Frozen Vegetables.
- ▣ **160.** §160.100–160.190. Eggs and Egg Products.
- ▣ **161.** §161.30–161.190. Fish and Shellfish.
- ▣ **163.** §163.5–163.155. Cacao Products.
- ▣ **164.** §164.110–164.150. Tree Nut and Peanut Products.
- ▣ **165.** §165.3–165.110. Beverages.
- ▣ **166.** §166.40–166.110. Margarine.
- ▣ **168.** §168.110–168.180. Sweeteners and Table Sirups.
- ▣ **169.** §169.3–169.182. Food Dressings and Flavorings.
- ▣ **170.** §170.3–170.285. Food Additives.
- ▣ **179.** §179.21–179.45. Irradiation in the Production,
Processing and Handling of Food.
- ▣ **190.** §190.6. Dietary Supplements.
- ▣ **501.** §501.1–501.110. Animal Food Labeling.
- ▣ **507.** §507.1–507.215. Current Good Manufacturing
Practice, Hazard Analysis, and Risk-Based
Preventive Controls for Food for Animals.
- ▣ **570.** §570.3–570.280. Food Additives.
- ▣ **579.** §579.12–579.40. Irradiation in the Production,
Processing, & Handling of Animal & Pet Food.

Note: List is not exhaustive. Other regulations may be applicable.

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey
 Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

21 C.F.R. §1.500 – §1.514

The following section(s) of the FSVP regulation is/are or may be particularly relevant to this product/supplier.

- | | |
|--|--|
| <ul style="list-style-type: none"> ▣ §1.500. What Definitions Apply to This Subpart? ▣ §1.501. To What Foods Do the Requirements in This Subpart Apply? ▣ §1.502. What Foreign Supplier Verification Program (FSVP) Must I Have? ▣ §1.503. Who Must Develop My FSVP and Perform FSVP Activities? ▣ §1.504. What Hazard Analysis Must I Conduct? ▣ §1.505. What Evaluation for F. Supplier Approval & Verification Must I Conduct? ▣ §1.506. What Foreign Supplier Verification and Related Activities Must I Conduct? ▣ §1.507. What Requirements Apply When I Import Food That Cannot Be Consumed Without the Hazards Being Controlled or for Which the Hazards Are Controlled After Importation? | <ul style="list-style-type: none"> ▣ §1.508. What Corrective Actions Must I Take Under My Foreign Supplier Verification Program? ▣ §1.509. How Must the Importer Be Identified at Entry? ▣ §1.510. How Must I Maintain Records of My FSVP? ▣ §1.511. What FSVP Must I Have If I Am Importing A Food Subject to Certain Requirements in the Dietary Supplement Current Good Manufacturing Practice Regulation? ▣ §1.512. What FSVP May I Have If I Am A Very Small Importer or I Am Importing Certain Food from Certain Small Foreign Suppliers? ▣ §1.513. What FSVP May I Have If I'm Importing Certain Food from A Country with An Officially Recognized Food Safety System? ▣ §1.514. What Are Some Consequences of Failing to Comply with the Requirements of FSVP? |
|--|--|

NOTES & COMMENTS

FSVP 21 CFR §1.500–§1.514

This product falls – at least in part – under the jurisdiction of the United States Food and Drug Administration (FDA), and does not qualify for an exemption in Title 21, Code of Federal Regulations, Chapter I, Sub-chapter A, Part 1, Subpart L, §1.501. As the FSVP Importer's Qualified Individual (as the term is defined in §1.503) United Safety Agents – through the actions of this FSVP Plan's identified "Agent(s)" – has performed all actions required by FSVP and has presented this FSVP Plan for the review of this product's FSVP Importer. Please refer to pages 27 through 35 for substantiation of the FSVP QI's / PCQI's qualifications and certifications.

Per §1.513, this food is imported from a country with an officially recognized or equivalent food safety system and the above-named facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law including relevant laws and regulations of foreign countries.

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

ATTESTATION *of* REVIEW & ASSESSMENT

21 C.F.R., §1.506, (d)(3) provides that “You may rely on a determination of appropriate foreign supplier verification activities . . . made by an entity other than the foreign supplier if you review and assess whether the entity’s determination regarding appropriate activities. . . . You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual.” **Please review this FSVP plan in its entirety and document your review below.**

I, _____ *type name* _____ certify that I reviewed this FSVP plan on _____ *today's date* _____ and found its contents to be acceptable.

Reviewer's Name: _____

Reviewer's Signature: _____

Reviewer's Title: _____

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey
 Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

DESIGNATION of ROLES & SUMMARY of REVIEW

FOREIGN SUPPLIER VERIFICATION PROGRAM IMPORTER

Company Name: Tuff Bear, LLC FDA FEI: _____
 Physical Address: 1013 North 3rd Avenue DUNS No.: 07-479-6267
 City: Wausau State: Wisconsin Country: United States
 Mailing Address: 1013 North 3rd Avenue
 City: Wausau State: Wisconsin Country: United States
 Phone Number: +1 (715) 574-3952 Email Address: sales@tuffbear.com
 Name of Representative(s): Mr. Warren Pope Title: Owner / Commercial Rep.

FOREIGN SUPPLIER &/OR MANUFACTURER as defined by §1.500

Company Name: Bee's Inn FDA FFR: 16802114790
 Manufacturing Address: 27 West Road Road 1 FDA FEI: 3012086164
 City: Ohaupo Province/Territory: Waikato, 3881 Country: New Zealand
 Office Address: NZ Post Centre, 106A Great South Road
 City: Ohaupo Province/Territory: Waikato, 3881 Country: New Zealand
 Phone Number: 07 823 6513 Email Address: dave-west@xtra.co.nz
 Name of Representative(s): Mr. David West Title: Commercial Rep.

QUALIFIED INDIVIDUAL(s) & AGENT(s)

Agent/QI Name: Claudio Innocenti Signature: 
 Title: Partner & Preventive Controls Qualified Individual. Date: April 17, 2021
 Agent/QI Name: William J. Barber Signature: 
 Title: Preventive Controls Qualified Individual. Date: April 17, 2021

SUMMARY of REVIEW

Details of Product(s)	Is foreign supplier expected to implement controls for			Comments
	Biological Hazards	Chemical Hazards	Physical Hazards	
Rewarewa and Manuka Honey.	☒ Yes ☐ No ☐ Undetermined	☒ Yes ☐ No ☐ Undetermined	☒ Yes ☐ No ☐ Undetermined	Verified & Approved. See Addendum.
Rewarena Honey	☐ FSVP Importer	☒ FSVP Importer	☐ FSVP Importer	
Manuka Honey UMF 5+	☐ Disclosure	☐ Disclosure	☐ Disclosure	
Manuka Honey UMF 10+	☐ Customer	☐ Customer	☐ Customer	

Preventive Control or Disclosure Rqd.: Per §117, §507, §111 and/or §1.507, Notice is required when FSVP Importer or FSVP Importer's customer will be responsible for controlling hazards. See "Hazard Analysis & Determination" section(s) and "Addendum" section for additional information. ■ Required ■ Recommended ■ Confirm efficacy of previously applied control(s)

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

REGISTER of SUBSTANTIATING DOCUMENTS



HAZARD ANALYSIS

☒ Requested ☐ Required ☐ Received ☐ Reviewed

NOTES Bee's Inn's HACCP Plan received.

Dated: April 2021.

Plan Entitled: HACCP plan for the production of Honey at 27 West Road, Ohaupa.

Contains: Hazard Analysis, Critical Control Points, Critical Limits, Monitoring, Corrective Actions, Verification, and Documentation.

Bee's Inn's HACCP Application Procedures received.

Ministry for Primary Industries, Operational Code: Processing of Bee Products

Dated: December 15, 2017.



ON-SITE AUDIT

☒ Requested ☐ Required ☐ Received ☐ Reviewed

NOTES Bee's Inn's RMP & OAS Verification Audit - Limited Scope Processor Audit Report received.

Dated: November 30, 2020.

Re-audit Due Date: 6 months.

Audit Grade: Acceptable

Number of Minor Non-conformities: A total of 1 non-conformances were raised as a result of this assessment and will need to be closed out by the action by date. A total of 5 observations were noted in the interests of continued improvement.

Note: On-site audit report was not relied upon to approve this foreign supplier.



SAMPLING OR TESTING RESULTS

☒ Requested ☐ Required ☐ Received ☐ Reviewed

NOTES Certificate of Analysis received from supplier.

Dated: April 12, 2021.

Tested for: Pesticides.

Laboratory: Analytica Laboratories.

Note: We recommend that recent certificate(s) of analysis be acquired by importer for testing conducted to determine that product has been effectively processed to control for all FDA identified biological and chemical hazards (preferably by an ISO 17025-accredited laboratory).



OTHER FOOD SAFETY RECORDS

☒ Requested ☐ Required ☐ Received ☐ Reviewed

NOTES Completed Foreign Supplier FSVP Questionnaire received.

Dated: April 14, 2021.

Completed by: Christine West.

Receipt of Incoming Honey for Process and Packing Procedures received.

Personal Competencies and Training Procedures received.

Hygienic Practices Procedures received.

Procedures for Non-conforming Product and Recall received.



PRODUCT LABELING

☒ Requested ☐ Required ☐ Received ☐ Reviewed

NOTES Product Label received. Label clearly identifies any present allergens. Labeling is in compliance with Part 403(w) of the Federal Food, Drug, and Cosmetic Act in so far as it is not misbranded with respect to the presence of food allergens. See Analysis & Determination of Allergenic Hazard(s) for details.

Note: USA's assessment of product(s) labeling is restricted to a label(s)' allergen disclosure statement and should not be interpreted to mean that the label(s) meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food Allergen Labeling and Consumer Protection Act (FALCPA), or any other applicable section of 21 CFR Part 101.. USA recommends that FSVP Importer independently confirm that product label(s) is in compliance with all regulations prior to import.

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

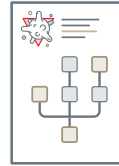
VERIFICATION FREQUENCY *for* UPDATED DOCUMENTS

21 C.F.R., §1.505, §1.506, and §1.510 require that all FSVP records be updated and maintained. Depending on USA's review and determination of the supplier's compliance history and food safety program, the following food safety documents will be required accord to their individually-marked time interval.



FACILITY FOOD SAFETY PLAN

- ☒ if a change or update occurs
- ☐ annual basis (*regardless of change*)
- ☐ other: _____



RECALL PLAN

- ☒ if a change or update occurs
- ☐ annual basis (*regardless of change*)
- ☐ other: _____



HACCP PLAN / HARPC PLAN

- ☒ if a change or update occurs
- ☐ annual basis (*regardless of change*)
- ☐ other: _____



PRODUCT LABEL

- ☒ if a change or update occurs
- ☐ annual basis (*regardless of change*)
- ☐ other: _____



ON-SITE AUDIT RESULTS

- ☒ if a change or update occurs
- ☐ annual basis (*regardless of change*)
- ☐ other: _____



QUALIFICATIONS

- ☒ if a change or update occurs
- ☐ annual basis (*regardless of change*)
- ☐ other: _____



LABORATORY TESTING RESULTS

- ☒ if positive results are returned
- ☒ if recall or import refusal occurs
- ☒ if inspection occurs
- ☒ on an annual basis
- ☐ on a per-batch/shipment basis
- ☒ Chemical ☒ Biological
- ☐ other: _____



IMPLEMENTATION RECORDS

- ☒ if recall or import refusal occurs
- ☒ if inspection occurs
- ☐ on an annual basis
- ☐ on a per-batch/shipment basis
- ☐ other: _____



FDA REGISTRATION

- ☒ if a change or update occurs
- ☒ bi-annual basis (*regardless of change*)



FSVP QUESTIONNAIRE

- ☒ if a change or update occurs
- ☐ annual basis (*regardless of change*)
- ☐ other: _____



FACILITY LICENSE

- ☐ if a change or update occurs
- ☐ annual basis (*regardless of change*)
- ☒ not applicable



NOTES

All documents used for FSVP verification and approval must be re-acquired at least one every three years or sooner, per above.

unitedsafetyagents.com/documents

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

FDA COMPLIANCE ACTIONS & REGULATORY HISTORY

21 CFR part 1, subpart L, §1.505(a)(1)(iii)(A)(C), and elsewhere requires that a foreign supplier's compliance history be evaluated, including whether the foreign supplier is the subject of an FDA Warning Letter(s), Import Alert(s), or other FDA compliance action(s) related to food safety. The following constitutes the results of this evaluation.

RESULTS of EVALUATION

Date of Action	Description of Action
N/A	FDA Data Dashboard search results indicate that supplier's compliance history does not include FDA Warning Letters, Import Alerts, or other applicable compliance actions.

Note: Results may not be exhaustive. FSVP Importer should conduct independent inquiry.

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

REVISION LOG *for* FSVP PLAN

Version No.	Date of Change	Description of Revision
No. 01	April 13, 2019	Product and supplier underwent initial FSVP verification.
No. 02	April 16, 2020	Foreign Supplier and product underwent annual verification. Additional and/or updated food safety documents were requested, received, and added to FSVP. FSVP content and format was updated to reflect recent FDA Guidance document(s) and/or regulatory statutes that became applicable since initial verification, or previous reverification.
No. 03	April 17, 2021	Foreign Supplier and product underwent annual verification. Additional and/or updated food safety documents were requested, received, and added to FSVP. FSVP content and format was updated to reflect recent FDA Guidance document(s) and/or regulatory statutes that became applicable since initial verification, or previous reverification.

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

ANALYSIS & DETERMINATION of BIOLOGICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☐ <i>Bacillus cereus</i> ☒ <i>Clostridium botulinum</i> ☐ <i>C. perfringens</i> ☐ <i>Brucella spp.</i> ☐ <i>Campylobacter spp.</i> ☐ <i>Pathogenic E. coli</i> ☐ <i>Salmonella spp.</i> ☐ <i>S. aureus</i> ☐ <i>L. monocytogenes</i> ☐ <i>Trichinella spiralis</i> ☐ <i>Giardia lamblia</i> ☐ <i>Shigella spp.</i> ☐ <i>Other</i>	<1	2	Biological hazards can be effectively controlled through the utilization of a number of different control measures, including – but not limited to – the application of a heat and/or chemical kill-step, implementing and following raw material supplier approval procedures, subjecting raw material(s) and/or finished product(s) to laboratory testing, and/or through the utilization of a number of other appropriate control measures. ———— SUPPLIER CONTROL MEASURES ———— 01. Supplier utilizes raw material supplier approval procedures to control for hazards posed by biological agents. Details: Biological hazards include; pathogenic microorganisms - <i>Clostridium</i> spp, <i>Bacillus</i> spp. Visual inspection and removal of infested combs and good hygienic practices will minimize contamination i.e. cleaning of the pricker and equipment i.e. uncapping knife. Honey supers are to be covered when transporting honey to the processing factory to minimize contamination. Details: <i>Clostridium botulinum</i> - risk medium. Ensure all equipment is thoroughly cleaned using approved cleaning maintenance compound - microdect 750B 10 - 20ml per litre of water applied at a temperature of 60c for 10-20 minutes then washed off and dried before use. ———— NOTE ———— 00. Honey has good antibacterial activity against numerous microorganisms of many different genera. Likelihood of hazard is very low. We respectfully request a copy of Bee's Inn's supplier approval procedures and independent laboratory testing results for biological hazards (if available).	Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control FDA identified biological hazards. USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified biological hazards. ----- HAZARD PROFILE ----- ----- SOURCE ----- Appendix 1 (Hazards Tables) Category: Food Sweeteners. Category No.: 03. Subcategory: Honey (Liquid).

Legend for Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.

C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.

P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

Probability (P): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))

Severity (S): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))

P. & S. Assessment Scale: 1 - Low, 2 - Moderate, 3 - High, 4 - Serious adverse health consequences or death.

Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

ANALYSIS & DETERMINATION of CHEMICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☒ Drug residues ☐ Heavy metals ☐ Industrial chemicals ☒ Pesticides ☐ Mycotoxins/Toxins ☐ Radiological ☐ Unapproved colors & additives ☒ Chemical hazards due to mis-formulation ☐ Other	1	2	Chemical hazards can be effectively controlled through the utilization of a number of different control measures, including – but not limited to – implementing and following appropriate raw material supplier approval procedures, and/or subjecting raw material(s) and/or finished product(s) to laboratory testing. ———— SUPPLIER CONTROL MEASURES ———— 01. Supplier utilizes laboratory testing to control hazards posed by chemical agents. 02. Supplier also utilizes CGMPs (for beekeeping) and raw material supplier approval procedures to control for hazards posed by chemical agents. Details: Each consignment of honey is to have a Harvest Declaration to confirm the controls applied are intended to minimize the risks to human health from agricultural chemicals - pesticides, herbicides and Tutin in honey. Details: A register of approved and non-approved maintenance chemical compounds is to be kept. Measuring containers are to be labelled for chemical use only. Personnel are to be trained in the correct handling and use of chemicals. Directions posted on the wall. Equipment and contact surfaces are to be thoroughly washed off after exposure to any maintenance compound. Empty chemical containers are to be disposed of according to manufacturer's instructions and not re-used for any purpose within the facility. ———— NOTE ———— USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified chemical hazards.	Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control FDA identified chemical hazards. USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified chemical hazards. ----- HAZARD PROFILE ----- ----- SOURCE ----- Appendix 1 (Hazards Tables) Category: Food Sweeteners. Category No.: 03. Subcategory: Honey (Liquid).

Legend for Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.

C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.

P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

Probability (P): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))

Severity (S): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))

P. & S. Assessment Scale: 1 - Low, 2 - Moderate, 3 - High, 4 - Serious adverse health consequences or death.

Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

ANALYSIS & DETERMINATION of ALLERGENIC HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☐ Undeclared allergens - Incorrect label ☐ Undeclared allergens - Cross-contact ALLERGENS ☐ Milk ☐ Eggs ☐ Fish ☐ Shellfish (<i>Crustacean</i>) ☐ Tree nuts ☐ Peanuts ☐ Wheat ☐ Soybeans ☐ Sesame*	—	3	Allergens themselves can not be directly controlled. However, the presence of allergens – or a given allergen – can be controlled. The presence of allergenic hazards can be effectively controlled through the utilization of a number of control measures, including – but not limited to – staff training for common food allergens, avoiding cross-contact, and proper food labeling. These may be effective methods to ensure that allergens are not ingested by a person who will be experience a negative reaction. ———— SUPPLIER CONTROL MEASURES ———— 01. Supplier certifies that: A) there are NO allergens handled on site. B) a documented allergen control program is in use. C) a dedicated process line and a documented cleaning procedure are in place to prevent contamination. D) all employees undergo allergen training and processes have been put in place to reduce the likelihood of cross contact or unintentional introduction of allergens into processing area. E) Honey is to be tested for Tutin by an Accredited Laboratory before sale. ———— NOTE ———— ----- Labeling Requirements ----- - Food Allergen Labeling and Consumer Protection Act - ----- - Nutritional information (not appliance to bulk). - Name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5). - Quantity of contents (21 CFR 101.7). - Statement of identity (21 CFR 101.3). - Presence of artificial flavoring, artificial coloring, or chemical preservative (21 CFR 101.22). - Ingredient statement if the product has two or more ingredients (21 CFR 101.4). - Presence of major food allergens (21 U.S.C. 343(w)). - Percent juice (21 CFR 101.30), when applicable.	Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control the hazard posed by allergenic adulteration. Note: USA's assessment of product(s) labeling is restricted to a label(s)' allergen disclosure statement and should not be interpreted to meant that the label(s) meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food Allergen Labeling and Consumer Protection Act (FALCPA), or any other applicable section of 21 CFR Part 101. USA recommends that FSVP Importer independently confirm that product label(s) is in compliance with all applicable regulations prior to import. ----- HAZARD PROFILE ----- ----- SOURCE ----- Appendix 1 (Hazards Tables) Category: Food Sweeteners. Category No.: 03. Subcategory: Honey (Liquid).

Legend for Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.

C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.

P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

Probability (P): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))

Severity (S): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))

P. & S. Assessment Scale: 1 - Low, 2 - Moderate, 3 - High, S - Serious adverse health consequences or death.

Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

*Per Food Allergy Safety, Treatment, Education and Research Act, food packages will need to reflect allergen labeling for sesame beginning on January 1, 2023.

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey
 Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

ANALYSIS & DETERMINATION of ENVIRONMENTAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☐ Recontamination with environmental pathogens. ☐ Bacterial pathogen survival of a lethal treatment. ☐ Bacterial growth and/or toxin formation due to lack of time / temperature control. ☐ Recontamination due to lack of container integrity. ☐ Bacterial growth and/or toxin formation due to poor formulation control. ☐ Bacterial growth and/or toxin formation due to reduced oxygen packaging. ☐ Other	1	2	Hazards posed by ineffective processes or environmental pathways can be controlled by the utilization of Current Good Manufacturing Practices, positively releasing finished product, avoiding cross-contamination, carefully monitoring production process, subjecting raw material(s) and/or finished product(s) to laboratory testing, and/or through the utilization of a number of other appropriate control measures. ———— SUPPLIER CONTROL MEASURES ———— 01. The FDA does not recognize any processes or environmental hazards in reference to this product type. Appendix 1 (Hazards Tables) Category: Food Sweeteners. Subcategory: Honey (Liquid).	Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control FDA identified environmental hazards. USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified environmental hazards. ----- HAZARD PROFILE ----- ----- SOURCE ----- Appendix 1 (Hazards Tables) Category: Food Sweeteners. Category No.: 03. Subcategory: Honey (Liquid).

Legend for Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.
C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.
P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.
Probability (P): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))
Severity (S): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))
P. & S. Assessment Scale: 1 - Low, 2 - Moderate, 3 - High, 4 - Serious adverse health consequences or death.
Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey
 Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

ANALYSIS & DETERMINATION of PHYSICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☒ Metal ☒ Glass ☐ Extraneous Matter ☐ Plastics ☐ Stones ☐ Wood ☐ Natural Component of Food ☐ Other	1	2	Physical hazards can be effectively controlled through the utilization of a number of different control measures, including – but not limited to – the utilization of an operational and calibrated metal detector during and/or after the production process, sieving raw material and/or finished product, optical sorting machinery, visual inspection, appropriate and consistent raw material supplier approval methods, and/or through the utilization of a number of other appropriate control measures. ———— SUPPLIER CONTROL MEASURES ———— 01. Supplier utilizes visual inspection and filtering/straining to control hazards posed by physical agents. 02. Supplier also utilizes a glass/breakable plastic policy. 03. Supplier sieves finished products. ———— NOTE ———— ----- Internal SOPS ----- 01. Dust/Dirt - Do not place supers of honey directly on the ground. Place on clean stainless steel drip trays in the apiary, during transport and in the extraction area. 02. Insect debris and wax particles - Use double filtration down to 200 micron. 03. Honey jars - inspect honey jars prior to filling - discard any damaged or contaminated containers. 04. Metal - Regularly inspect all metal tools and equipment for wear, rust or damage. Do not use honey if contamination is found.	Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control physical hazards. ----- HAZARD PROFILE ----- ----- SOURCE ----- Appendix 1 (Hazards Tables) Category: Food Sweeteners. Category No.: 03. Subcategory: Honey (Liquid).

Legend for Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.
C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.
P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.
Probability (P): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))
Severity (S): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))
P. & S. Assessment Scale: 1 - Low, 2 - Moderate, 3 - High, 4 - Serious adverse health consequences or death.
Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey
Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

ASSESSMENT of FOREIGN SUPPLIER

1.0 SUPPLIER INFORMATION

- 1.1. Supplier name: Bee's Inn
- 1.2. Supplier address: 27 West Road Road 1, Ohaupo, Waikato, 3881, New Zealand.
- 1.3. Products manufactured/supplied: Rewarewa and Manuka Honey.
- 1.4. Is the supplier certified to a food safety standard and audited regularly? ☐ Yes ☐ No ☒ N/A
GFSI Standard: _____
- 1.5. Is the standard GFSI benchmarked/recognized? ☐ Yes ☒ No ☐ Other (see Addendum)
- 1.6. Has the supplier provided specifications? ☒ Yes ☐ No
- 1.7. Has the supplier completed a Supplier Assessment and an Allergen Questionnaire? ☒ Yes ☐ No
- 1.8. Have the supplier's specifications and/or completed questionnaires been evaluated by USA's PCQI(s)?
☒ Yes ☐ No PCQI(s): C. Innocenti (PCQI. Member, USA LLC)

2.0 SUPPLIER PROCEDURES, PROCESSES & PRACTICES

- 2.1. Does supplier follow current GMPs? ☒ Yes ☐ No
- 2.2. Does the supplier have SOP in place for each procedure in the production & release of product? ☒ Yes ☐ No ☐ N/A
- 2.3. Does the supplier have allergen controls in place to prevent cross-contamination? ☒ Yes ☐ No ☐ N/A

3.0 SUPPLIER PERFORMANCE HISTORY

- 3.1. Does the supplier have a HACCP/PC plan for each product manufactured for the importer? ☒ Yes ☐ No ☐ N/A
- 3.2. Has the supplier's HACCP/PC plan been reviewed and approved by USA's PCQI(s)? ☒ Yes ☐ No
PCQI(s): C. Innocenti (PCQI. Member, USA LLC)
- 3.3. To the best of USA's knowledge, has the supplier been the subject of a public FDA Alert/Warning Letter?
☐ Yes ☒ No ☐ N/A Description: No, Import Alert & Warning Letter search-results, which were conducted on – or about – the Review End date, have been attached to this FSVP Plan.
- 3.4. Has the supplier supplied a product that needed to be recalled for a food safety reason? ☐ Yes ☒ No ☐ N/A
Description: No, as of this FSVP Plan's Review End date, USA has no knowledge of any recall undertaken by supplier.

Continued onto next page.

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

ASSESSMENT of FOREIGN SUPPLIER

3.0 SUPPLIER PERFORMANCE HISTORY (Continued)

3.5. Has the supplier supplied out of specification product excluding quality issues? ☐ Yes ☒ No ☐ N/A

3.6. Has importer conducted microbiological testing for all lots imported from the supplier? ☐ Yes ☐ No ☒ N/A

3.7. Has any lot tested positive for chemical, physical or biological hazards? ☐ Yes ☒ No ☐ N/A

Description of the incident and the corrective actions taken by the supplier: No, as of this FSVP Plan's Review End date, USA has no knowledge of any lot/batch testing positive for any FDA-identified hazard(s).

3.8. Has the supplier provided timely and adequate responses to all requests and issues related to food safety?

☒ Yes ☐ No

Description: Yes, supplier (either directly, or through the FSVP Importer) has provided timely and adequate responses to our inquiries and requests.

4.0 SUPPLIER APPROVAL

4.1 Have USA's PCQI(s) identified and evaluated the known and reasonably foreseeable hazards for each product imported from the supplier and are there preventive controls in place to adequately control the hazards?

☒ Yes ☐ No

PCQI(s): C. Innocenti (PCQI. Member, USA LLC)

4.2. After reviewing all hazards and the supplier's performance, have USA's PCQI(s) determined appropriate verification activities that will be conducted and documented on an ongoing basis to verify the preventive controls are effectively controlling the hazard(s)? ☒ Yes ☐ No

PCQI(s): C. Innocenti (PCQI. Member, USA LLC)

4.3 Is the foreign supplier approved for import into the United States under this FSVP plan? ☒ Yes ☐ No

Comments: Supplier has been verified and their products have been approved for importation.

Additional Recommendations:

USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified hazards.

Supplier follows CGMPs and utilizes an established food safety program. Products supplied by this supplier have been verified and are approved for import. Supplier/product will be re-assessed and re-verified to the standards of the Foreign Supplier Verification Program on an annual basis (or sooner if necessary). This FSVP will expire one year from its above the above noted "Review End" date.

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

REVIEW of GENERAL FOOD SAFETY PROGRAM

Claims Made Against Product

No claims have been made against the raw material / product type.

Reference materials in the public domain define honey as “a thick, sweet, syrupy substance that bees make as food from the nectar of plants or secretions of living parts of plants and store in honeycombs.”² FDA has concluded that this definition accurately reflects the common usage of the term “honey.”

Overview of Foreign Supplier's Commercial Operation

The operators, Chris and Dave operate Bee's Inn as part of their beekeeping business, which focuses on production of honey and providing pollination services.

Note: The previous plant burnt down in April 2019 and the operators are in the process of rebuilding a new facility on the existing concrete pad. Stage one is complete and operational and consists of an office, an extraction room, a packing room, and a hot room. The latter is currently operating as a storage area. Stage 2 is the larger storage area and is currently framed up and awaiting a roof and wall cladding.

Ongoing verification will be required upon completion of new plant.

Testing Program & Accreditation

Supplier certifies that laboratory testing is a part of their food safety program, but has not provided testing result.

USA recommends that FSVP Importer conduct independent laboratory testing on product samples (preferably by an ISO 17025-accredited laboratory) on a regular basis to confirm that supplier has effectively controlled (and continues to control) all FDA identified environmental hazards.

Supplier & Product Allergen Information

Supplier certifies that: A) there are NO allergens handled on site, B) a documented allergen control program is in use, C) a dedicated process line and a documented cleaning procedure are in place to prevent contamination, D) all employees undergo allergen training and processes have been put in place to reduce the likelihood of cross contact or unintentional introduction of allergens into processing area.

Note: USA's assessment of product(s) labeling is restricted to a label(s)' allergen disclosure statement and should not be interpreted to mean that the label(s) meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food Allergen Labeling and Consumer Protection Act (FALCPA), or any other applicable section of 21 CFR Part 101. USA recommends that FSVP Importer independently confirm that product label(s) is in compliance with all applicable regulations prior to import.

Packaging Type & Shipping / Handling Requirements

Supplier certifies that packaging is accredited for food use. Ambient shipping and handling requirements.

Labeling of retail packs as specified in the Food Standards Code.

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

REVIEW of GENERAL FOOD SAFETY PROGRAM

Supplier GFSI Status & Historical Performance

Supplier appears to be following CGMPs and utilizes an established food safety program. Products supplied by this supplier have been verified and are approved for import.

Close Supplier Monitoring

Yes. The previous plant burnt down in April 2019 and the operators are in the process of rebuilding a new facility on the existing concrete pad. Stage one is complete and operational and consists of an office, an extraction room, a packing room, and a hot room. The latter is currently operating as a storage area. Stage 2 is the larger storage area and is currently framed up and awaiting a roof and wall cladding.

Ongoing verification will be required upon completion of new plant.

Supplier/product will be re-assessed and re-verified to the standards of the Foreign Supplier Verification Program on an annual basis, or sooner if necessary.

General Comments & Verification Timeline

Supplier follows CGMPs and utilizes an established food safety program. Products supplied by this supplier have been verified and are approved for import. Supplier/product will be re-assessed and re-verified to the standards of the Foreign Supplier Verification Program on an annual basis (or sooner if necessary). This FSVP will expire one year from its above the above noted "Review End" date.

Instructions.

Verify that each shipment of creamed honey were produced by Bee's Inn, located at 27 West Road RD 1, Ohaupo, Waikato 3881, New Zealand by checking that the written assurance was provided and is current; and the bill of lading and/or the manufacturer's name on the product received.

If we determine that the foreign supplier of food does not produce the food consistent with the assurances the foreign supplier provided in accordance with 21 CFR 1.512; we will promptly determine and document whether we should continue to import the food from the foreign supplier, or discontinue use the foreign supplier, until the cause of adulteration or misbranding has been adequately addressed; and document any information, investigation and corrective actions taken.

NOTE

We respectfully request: Copy of Bee's Inn's supplier approval procedures and independent laboratory testing results for chemical and biological hazards.

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

ADDENDUM

NOTE

Labeling Requirements

The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 requires food manufacturers to label food products that contain an ingredient that is or contains protein from a major food allergen in one of two ways.

The first option for food manufacturers is to include the name of the food source in parenthesis following the common or usual name of the major food allergen in the list of ingredients in instances when the name of the food source of the major allergen does not appear elsewhere in the ingredient statement. For example: Vanilla Waffers Ingredients: Enriched flour (wheat flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, partially hydrogenated soybean oil, and/or cottonseed oil, high fructose corn syrup, whey (milk), eggs, vanilla, natural and artificial flavoring) salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin (soy), mono-and diglycerides (emulsifier)

The second option is to place the word "Contains" followed by the name of the food source from which the major food allergen is derived, immediately after or adjacent to the list of ingredients, in type size that is no smaller than the type size used for the list of ingredients. For example: Contains Wheat, Milk, Egg, and Soy

Food Allergen Labeling and Consumer Protection Act

- Nutritional information (not appliance to bulk).
- Name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5).
- Quantity of contents (21 CFR 101.7).
- Statement of identity (21 CFR 101.3).
- Presence of artificial flavoring, artificial coloring, or chemical preservative (21 CFR 101.22).
- Ingredient statement if the product has two or more ingredients (21 CFR 101.4).
- Presence of major food allergens (21 U.S.C. 343(w)).
- Percent juice (21 CFR 101.30), when applicable.

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

ADDENDUM

PROPER LABELING OF HONEY AND HONEY PRODUCTS

Misbranding

Under section 403(i) of the FD&C Act, a food is misbranded unless its label bears: (1) the common or usual name of the food, if there be any; and (2) the common or usual name of each ingredient, if the food is fabricated from two or more ingredients. The common or usual name for a food may be established by common usage or by regulation (21 CFR 102.5(d)). The common or usual name must accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients, and may not be "confusingly similar to the name of any other food that is not reasonably encompassed within the same name" (21 CFR 102.5(a)). Moreover, under 21 CFR 101.4(a)(1), ingredients required to be declared on the label or labeling of a food must be listed on its label by common or usual name in descending order of predominance by weight. Furthermore, under section 403(a)(1) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular.

Adulteration

Under section 402(b) of the FD&C Act, a food is adulterated if: (1) a valuable constituent has been omitted in whole or in part from a food; (2) if any substance has been substituted wholly or in part; (3) if damage or inferiority has been concealed in any manner; or (4) if a substance has been added to a food so as to increase its bulk or weight, reduce its quality or strength, or make it appear to be better or of greater value than it is.

Other

Additional labeling regulations can be found in section 403 of the FD&C Act and 21 CFR part 101, as other labeling requirements (e.g., net weight, nutrition facts) apply to honey. For more information, see FDA's Food Labeling Guide at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm>.

FOOD SAFETY MODERNIZATION ACT

The Preventive Controls rule would apply to honey producers who are required to comply with the FDA Food Facility Registration only. Those required to register will need to have a written food safety plan detailing their production practices relating to food safety. For more information on the preventive controls rule please visit the FDA FSMA website at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey
Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

ADDENDUM

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT



Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT



Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

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Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT



Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT



Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT



This is to certify that

William Barber

Has been awarded the

**Level 4 Award in HACCP Management for
Food Manufacturing
500/6523/3**

PASS

Date of Award
10 November 2016



Richard Burton

Richard Burton
Head of Qualifications



526405 101116 1107147



Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT

The Stewart Partnership

This is to Certify that

William James Barber

*Successfully completed a
Basic Principles of HACCP and
Internal Auditing
Course.*

*held at Elgar Foods Ltd,
Tenbury Wells,
from 17 - 18 February 2000*


.....
Partner.

Partners: Patrick S. Stewart, BSc, PhD, FRLA and C. Delyse Stewart B.A.

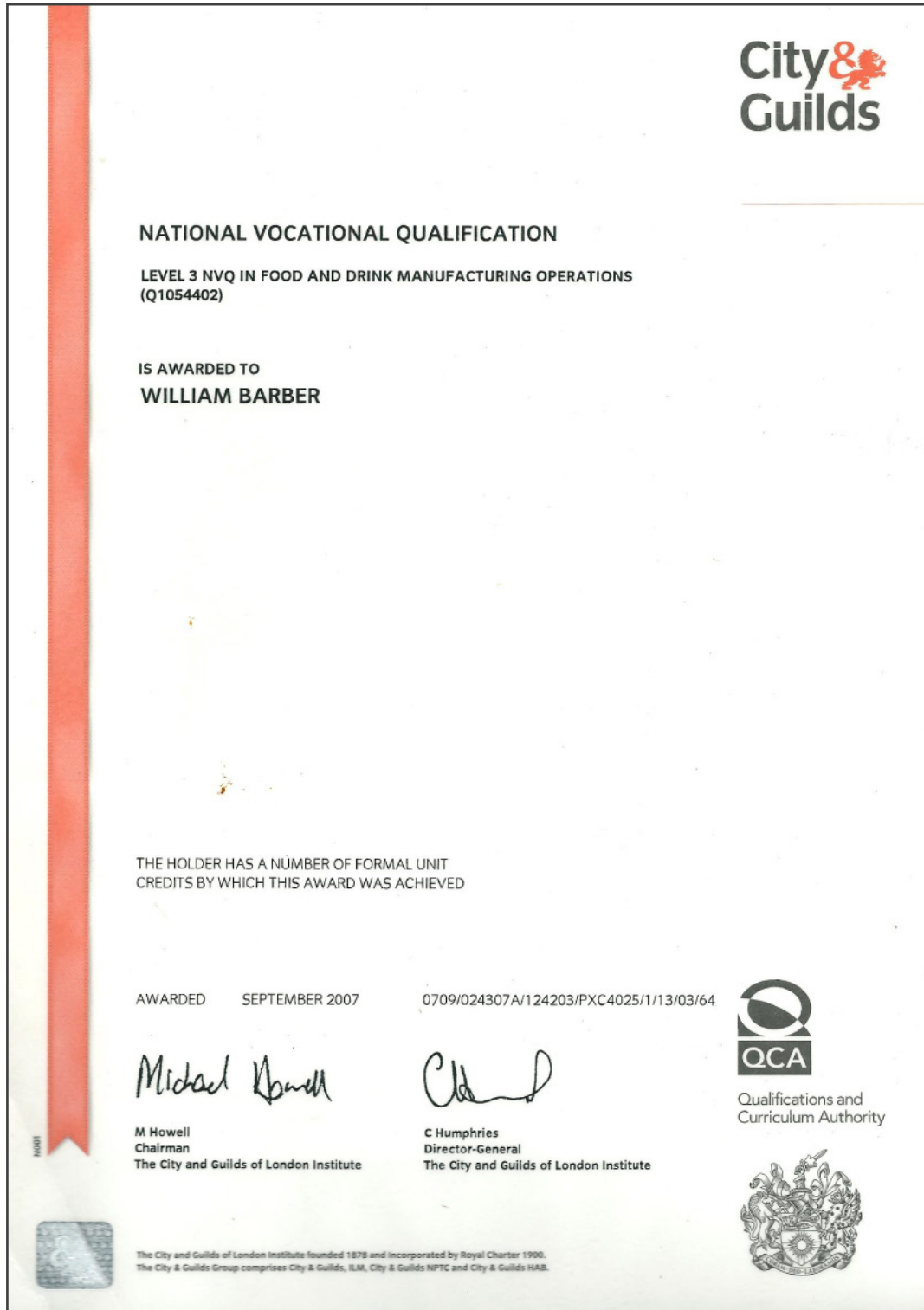
*The Stewart Partnership, 12, Burgess Wood Road South, Beaconsfield, Bucks, HP9 1EG, UK
Phone +44 (0) 1494 678240*

CERTIFICATE NUMBER 00/003

Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT



Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

CERTIFICATIONS & QUALIFICATIONS of FSVP AGENT



CERTIFICATE OF UNIT CREDIT TOWARDS
NATIONAL VOCATIONAL QUALIFICATION
LEVEL 3 NVQ IN FOOD AND DRINK MANUFACTURING OPERATIONS

IS AWARDED TO
WILLIAM BARBER

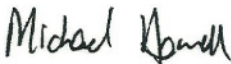
WHO ATTENDED PERSHORE GROUP OF COLLEGES

AND WAS SUCCESSFUL IN THE
FOLLOWING TEN UNITS

CONTROL AND MAINTAIN QUALITY WITHIN MULTI-STAGE MANUFACTURING OPERATIONS	U1024734
RESOLVE PROBLEMS IN MULTI-STAGE MANUFACTURING OPERATIONS	U1024735
MAINTAIN AND IMPROVE HEALTH AND SAFETY WITHIN THE WORKPLACE	U1024736
MAINTAIN AND IMPROVE HYGIENE AND PRODUCT SAFETY WITHIN THE WORKPLACE	U1024737
CONTRIBUTE TO THE ACHIEVEMENT OF ORGANISATIONAL AND PERSONAL GOALS	U1028661
PROVIDE INFORMATION TO SUPPORT DECISION MAKING	U1026144
MONITOR AND MAINTAIN THE HANDLING AND STORAGE OF MATERIALS	U1024742
IMPLEMENT QUALITY ASSURANCE SYSTEMS	U1027820
DEVELOP A FOOD AND DRINK PRODUCT	U1050274

CONTINUED

AWARDED SEPTEMBER 2007 0709/024307A/124203/PXC4025/1/13/03/64



M Howell
Chairman
The City and Guilds of London Institute



C Humphries
Director-General
The City and Guilds of London Institute



The City and Guilds of London Institute founded 1878 and incorporated by Royal Charter 1900.
The City & Guilds Group comprises City & Guilds, ILM, City & Guilds NPTC and City & Guilds HAB.



Supplier: Bee's Inn Product: New Zealand Rewarewa Honey and Manuka Honey

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 02, 2021 Review End: April 17, 2021

SUBSTANTIATING DOCUMENTS



This FSVP plan is based – at least in part – on the following foreign supplier-provided food safety document(s). All substantiating documents have been reviewed and assessed by United Safety Agents LLC.

Note All foreign supplier-provided document(s) are considered to be the property of that foreign supplier and may contain information which is privileged, confidential, and protected. Any reproduction, distribution or other use of these document(s) without the express written consent of the foreign supplier is prohibited. Enclosed document(s) are meant for review purposes only and are subject to change without notice. Document(s) may contain non-binding recommendations and are uncontrolled.

U.S. FOOD & DRUG ADMINISTRATION
FOREIGN SUPPLIER VERIFICATION PROGRAM

Recertification Questionnaire Submission

} Foreign Supplier
} **Bees Inn**
} Date: 2021-03-30

As required by 21 C.F.R., §1.506 (a); (a)(2); (b); (c); and elsewhere, all foreign supplier verification procedures and activities are to be conducted and/or re-conducted at a frequency appropriate to the relevant procedure/activity and the corresponding hazard profile for the relevant food. Based upon United Safety Agents' (USA) assessment of Bees Inn's operation, an annual recertification request for updated information and food safety documents has been sent out. The following pages contain the specifics of USA's request, along with Bees Inn's corresponding responses to each inquiry. *Note: Most questions can be properly interpreted, if preceded by "Within the past 400 days;"*

START

01) Has Bees Inn's Food Safety Plan or Program been revised in any way?

Response: **No**

02) Has Bees Inn's HACCP Plan been revised in any way?

Response: **No**

03) Has any change occurred to Bees Inn's product Ingredients?

Response: **No**

04) Has Bees Inn's Allergen Control Procedure been revised in any way?

Response: **No**

05) Has any change occurred to Bees Inn's product Labeling?

Response: **No**

06) Has Bees Inn's Onsite Audit report expired or been updated?

Response: **No**

07) Has Bees Inn undergone a recall, for any reason?

Response: **No**

U.S. FOOD & DRUG ADMINISTRATION
FOREIGN SUPPLIER VERIFICATION PROGRAM

Recertification Questionnaire Submission

} Foreign Supplier
} **Bees Inn**
} Date: 2021-03-30

08) Has Bees Inn been inspected by the United States Food & Drug Administration?

Response: **No**

09) Have any food items been stopped, held, or rejected by U.S. Customs, for any reason?

Response: **No**

10) Has the U.S. FDA issued Bees Inn a Warning Letter in relation to its facility or product(s)?

Response: **No**

11) Does Bees Inn perform laboratory analysis on its product(s)?

Response: **No**

12) Has any batch or lot tested positive for any biological or chemical hazard?

Response: **No**

13) Has Bees Inn's conformance with FSVP, or its appendant regulations, changed in any way?

Response: **No**

14) Are Bees Inn's products considered to be "Ready To Eat" when leaving its facility?

Response: **Yes**

14a) What hazard(s) remain uncontrolled?

Response:

15) Would you like to share any additional information?

Response: **No**

15a) Additional information:

Response:

U.S. FOOD & DRUG ADMINISTRATION
FOREIGN SUPPLIER VERIFICATION PROGRAM

Recertification Questionnaire Submission

} Foreign Supplier
} **Bees Inn**
} Date: 2021-03-30

C E R T I F I C A T I O N: By entering your name below, you certify that the information provided on and in connection with this form is true, accurate, and complete to the best of your knowledge. You understand that any false statements or deliberate omissions on this document – or any other document – that you provide to United Safety Agents may be grounds for disqualification from successful FSVP verification or, if discovered after FSVP approval takes place, could result in your product's FSVP approval status being revoked or terminated, and may result in your products or shipments being rejected from entry into the United States.

Certified by: **Christine Mary Lynette West**

Date of Certification: **2021-03-30**

Email Address of Respondent: **dave-west@xtra.co.nz**

—
END

HACCP plan for the production of Honey at 27 West Road. Ohaupo

2021

The purpose of this plan is to identify any risks associated with the production, extraction, filtration, packing and storage of Honey produced in (Location(s)) and processed at the above address which is intended for retail sale.

The plan consists of the following;

1. Hazard Analysis
2. Critical Control Points
3. Critical Limits
4. Monitoring
5. Corrective Actions
6. Verification
7. Documentation

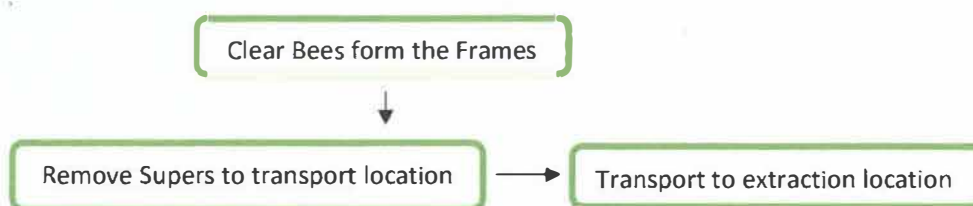
1. Hazard Analysis

Hazard Group	Specific Hazard	Risk	Control
Biological	Yeast	low	Ensure extracted product is kept in air tight containers and not exposed to air for extended periods of time. do not expose granulated honey to moisture or air to prevent fermentation
	Clostridium botulinum	Med	Ensure all equipment is thoroughly cleaned. Do not allow supers or Apiary equipment to sit directly on the ground. <i>Note:</i> Honey may contain spores as the product is not heated sufficiently to destroy the pathogen.
Chemical	Varoa, Apistan	Med	Follow manufacturer's instructions so veterinary products are not applied when supers are on the hive
	Insecticides	low	Store supers in stacks in containers to avoid wax moth infestation
	Preservatives	low	Only use products suitable for Bee Hives or do not treat hive bodies.
	Cleaning Agents	Med	Ensure manufacturer's instructions are followed for dilution rates and product limitations. Ensure diluted products are thoroughly rinsed off equipment before use.

	Toxic Plants And Pesticides	low	e.g. Tutin tested - if test fails blend Honey and retest to obtain a pass result. Lab tested by an accredited Laboratory, we use Analytica Laboratory. (Note: we have not had a fail result) Test for pesticides at an accredited Laboratory as per import country requirements
Physical	Dust/Dirt	med	Do not place full supers directly on the ground. Use stainless steel drip traps in the Apiary, during transport and in the extraction area. Ensure all equipment has been cleaned prior to use.
	Insect debris	low	Ensure double filtration down to 200 micron
	Wax particles	low	Ensure double filtration down to 200 micron
	Plastic	Low	Inspect jars prior to filling and reject damaged containers. Any damaged containers that are found are discarded.
	Wood	low	Ensure hives are sound and undamaged, do not continue to use damaged hive parts. Ensure double filtration to remove all particles
	Metal	Low	Regularly inspect all metal tools and equipment for wear, rust or damage. Double filter honey and do not use honey if contamination is found

Process steps

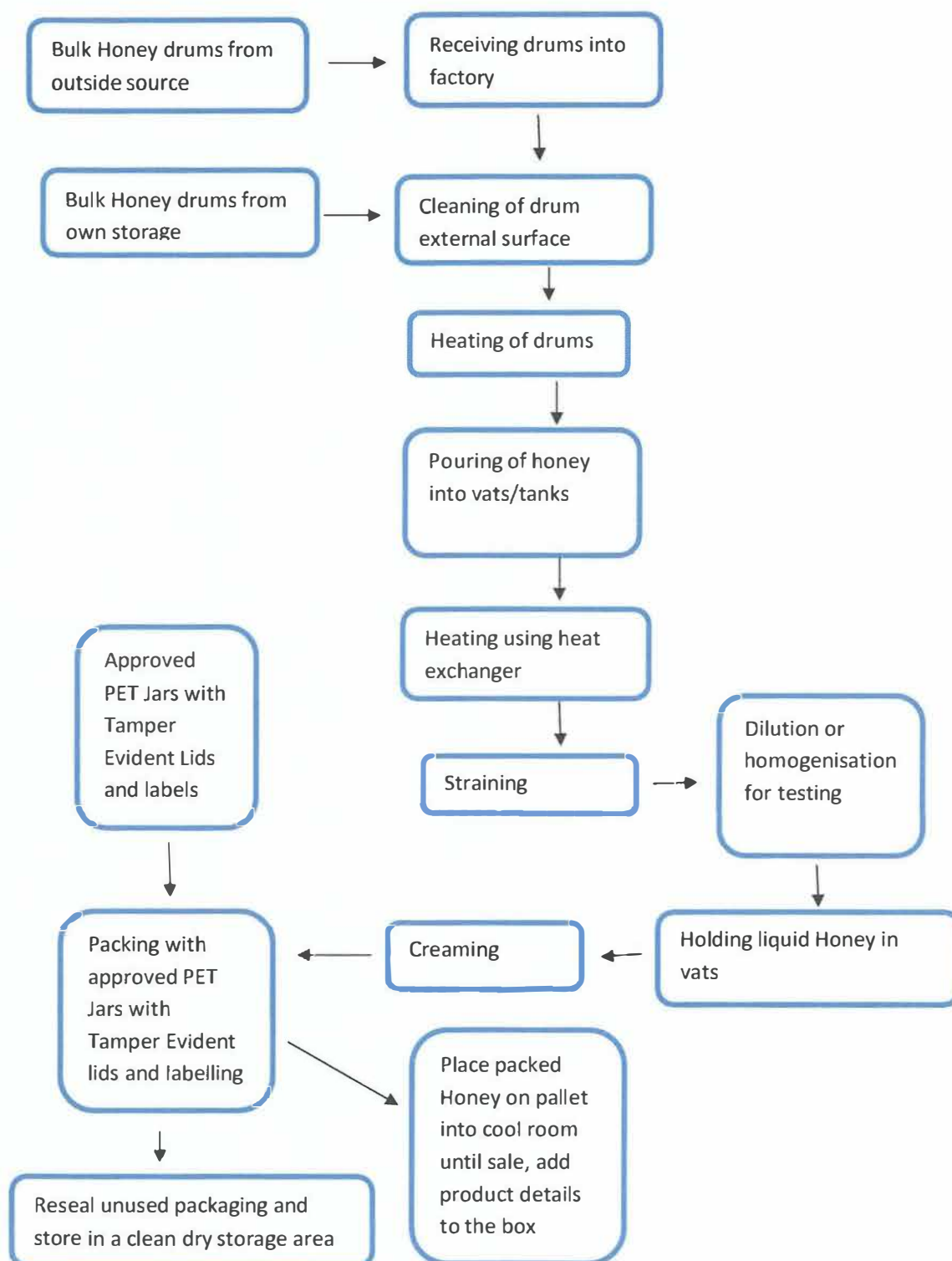
The process has been split into two sections to differentiate between primary production (in the Apiary) and the extraction process. Each CP and CCP has been identified through the process with reference points for the analysis.



Processing - extracting Honey



Packing of liquid and creamed Honey



2. Control Points

Control Point	Hazard	Control
2.1	Chemical residues from clearing of Bees from supers	We don't use chemical methods. We use bee blower to blow bees out of Honey super.
2.2	Contamination from dust, dirt and debris of supers removed from the hive	On the day Honey is taken off hives, all bees are blown off the frame and boxes of Honey stacked on clean stainless steel drip tray on pallet before transported to factory covered to eliminate contaminants and Bee incursions
2.3	Contamination from biological, physical and chemical elements on equipment and the workplace environment	Remove physical debris from all surfaces, use hot solution of cleaning agent to remove dirt, grease and pathogens from all surfaces. Rinse with clean potable water until all residues of cleaning agent and dirt has been removed. Dry surfaces with paper towel and leave to air dry before starting operation
2.4	Frames and extraction environment contaminated by insect incursion following the supers or hiding in the frames	Ensure the frames and supers are free from Bees, wasps and ants before entering the extraction area. Check that no other insects have entered the area before extraction begins. Check area is sealed, doors and windows closed.
2.5	Contamination of work surfaces from bee remains, honey, propolis, wax and external hive dirt	When extraction is complete and before filtration begins to separate 'dirty' process from final product filtration and preparation
2.6	Jars and lids contaminated and not suitable for filling	Discard all damaged containers and lids
2.7	Raising honey temperature above 40°C increasing the risk of HMF and Diastase	All Honey is warmed then filtered and cooled before going into the holding tank

3. Critical Limits

Critical Point	Limit	Test	Control	Corrective Action
Sugar Content	>60g/100g	refractometer	Extract only capped honey	Discard Honey use as Bee feed
Water Content	<20%	Refractometer	Test honey	If high in water blend or feed back to the Bees
HMF Value	<40mg/Kg	All Honey	Do not heat Honey	Discard Honey
Adulteration by feed solution	Nil	Refractometer and Organoleptic	Do not feed when supers are on the hive. Apply supers only in main nectar flow	Discard Honey use as Bee feed

4. Monitoring

Control Point	Who	When	What
4.1	Your Name	On the day honey is taken off	Examine super to ensure most Bees have moved out of the super. Physically clear each frame prior to transportation
4.2	Your Name	Before, during and after operation	Place clean stainless steel drip trays on a pallet on the truck deck. Cover supers for transport
4.3	Your Name	Prior to collection of supers from the Apiary	Visual check all surfaces for residues and moisture. Repeat cleaning process if anything found
4.4	Your Name	Before extraction can begin	Check supers before entering the extraction area. Once inside check environment before proceeding
4.5	Your Name	At the end of extraction and before filtration takes place	Seal Honey tanks and remove supers. Seal extractor. Clean all work surfaces
4.6	Your Name	During filtration process	In line, no Honey goes into buckets
4.7	Your Name	Before use of PET packaging	Visual inspection at each point. If any damage is found in packaging discard

5. Corrective Actions

Control Point	Hazard	Corrective Action
5.1	Chemical residues from clearing of Bees from supers	Ensure process involves physical clearing only using smoker
5.2	Contamination from dust, dirt and debris of supers removed from the hive	Brush off visible particles from frames. Place super onto clean stainless steel drip trays
5.3	Contamination from biological, physical and chemical elements on equipment and the workplace environment	Where unsatisfactory cleaning results are identified, repeat the cleaning process until satisfactory results are achieved
5.4	Frames and extraction environment contaminated by Insect incursion following the supers or hiding in the frames	Stop the process and clear the environment of insects Repeat cleaning process of equipment, work place and the environment
5.5	Contamination of work surfaces from bee remains, honey, propolis, wax and external hive dirt	Scrape super bodies with hive tool to reduce contamination, place super on a clean stainless steel drip tray and do not move from its intended location Repeat cleaning process of work place, equipment and the environment
5.6	Jars and lids contaminated and not suitable for filling	Discard any contaminated jars and lids
5.7	Raising honey temperature above 60°C increasing the risk of HMF and Diastase	Ensure working process and storage environment do not exceed the 60°C limit

6. Verification

Activity	Frequency	Comments
HACCP plan review	Annually from sign off date	From the date shown at the foot of this document
Document Control	Post cropping	As per section 7
Critical Limits	All stages of the process	In accordance with section 3

HACCP plan for the production of Honey at 27 West Road, Ohaupo

2021

7. Documentation

	Recommended Action	Details of actions	Date/sign
7.1 extraction room and tools	Clear and clean extraction room	Clean floors and work surfaces as per 5.3 Pass/fail -----	Date ----- Sign -----
	Clean and dry extractor	Clean floors and work surfaces as per 5.3 Pass/fail -----	Date ----- Sign -----
	Clean and dry honey filters, capping knife, drip tray, pricker, extractor	Clean floors and work surfaces as per 5.3 Pass/fail -----	Date ----- Sign -----
7.2 Bee feeding	A, Bee feeding after crop removal	Start date 10 March 2021 End date 31 May 2021	Date ----- Sign -----
	B, Liquid sugar	Proprietary feed may be used e.g. Chelsea Sugar NZ Litres: -----	Date ----- Sign -----
7.3 Bee Diseases	Varroa control measures in autumn and winter Apiguard Yes Apistan Yes Apivar Yes Oxalic Acid Yes	Batch No. ----- Batch No. ----- Batch No. ----- Batch No. -----	Date ----- Sign ----- Date ----- Sign -----
	Other diseases Name -----	Control ----- Details -----	Date ----- Sign -----
7.4 Super storage	Sealed stack	Details Sealed in containers	Date ----- Sign -----
7.5 Honey harvest, storage and labelling	Water content <20%	17% - 18%	Date ----- Sign -----
	Filtration 400 micron bulk 200 micron packed honey	Completed Y/N	Date ----- Sign -----

HACCP plan for the production of Honey at 27 West Road, Ohaupo

2021

	Bulk storage containers 200 litre food safe approved drums	No. 200 litre	Date ----- Sign -----
	Storage Temperature <20°C	Temp 14c	Date ----- Sign -----
	Labelling as per E.U regs	Country, Honey, Producer, address, country of Origin, weight, BBD, Lot No.	Date ----- Sign -----
		Lot No. ----- -	Date ----- Sign -----

Document Name	Version control	Next Review date	Sign	Date
HACCP PLAN for HONEY PRODUCTION	V.2	1 April 2022		

PROCEDURES FOR HACCP / HACCP APPLICATION

Hazards

Biological – include pathogenic microorganisms

Chemical - heavy metals, pesticides, veterinary medicines, Tutin

Physical - glass, metal fragments, plastic

Hazards may occur in the product as a result of:

- Contaminated raw materials or packaging
- process itself
- personnel, water, pests, wastes

Any contaminated product is to be labelled as such and kept in an area separate from honey that is suitable for human consumption.

All personnel to follow health and hygiene rules when processing honey

Chemical residues are from agricultural chemicals, and veterinary medicines, Tutin

Tutin maximum level is: 0.7mg/kg in all honey (except comb honey)

Compliance with requirements and

Option one

The last person to pack honey that is intended for sale for human consumption is responsible for testing for Tutin, at an accredited lab (Analytica or Hills) before sale of the honey and test results demonstrate the maximum level has not been exceeded.

Samples from multiple batches may be tested by the lab;

- if requested
- doing so will not compromise the test result
- the results are reported in a way that clearly indicates whether one or more of the combined samples may have exceeded the limit

Test results to be kept for four years from the date of when the honey was packed for human consumption. This option is not available for comb honey. A representative sample may be taken when filling a bulk container. This may be done before the honey is mixed into a homogenous batch or by core sampling honey from a drum.

A person must undertake at least one of the options in any of the clauses 2.3 to 2.7

Option two

Holding harvest records that demonstrate low risk harvest date

Option two is for the person to hold a written statement from the beekeeper supplying honey confirming the beekeeper holds records that demonstrate that the honey has been:

- . taken from the honey supers placed on hives after 1 July in any year and
- . removed from the hives by 31 December in the same year

Option three

Option 3 is for the person to request and hold a written statement from the beekeeper supplying the honey that confirms that the beekeeper holds records that:

- . identify the geographical location of all the hives from which the honey has been harvested (either on a topographical map at the standard scale of 1:50 000 or by global positioning system)

And

- . demonstrate that the tutu is not significantly present within the predictable range of bee foraging from those geographical locations.
- . The statement must be kept for four years from the date on which the honey is packed for sale for human consumption.

Option four

- . Holding records that demonstrate honey was harvested from apiaries below latitude 42 degrees south

- . identify the geographical location of all the hives from which the honey was harvested (either on a topographical map at the standard scale of 1:50 000 or by global positioning system)

And

- . confirm that each of those locations is situated below latitude 42 degrees south.
- . The statement must be kept for four years from the date on which the honey is packed for sale for human consumption.

Option five

Holding records that demonstrate low risk in areas by targeted testing of honey

- . Option five is for the person to request and hold a written statement from the beekeeper supplying honey that confirms that the beekeeper has records that:
 - . specify the location of all apiaries from which the honey is harvested for sale for human consumption
 - . Confirm that each apiary this option applies to, targeted honey samples have been tested for the presence of tutin each year for three consecutive years
 - . confirm that for each apiary this option applies to, targeted honey samples have been tested for the presence of tutin one year in every ten year period after the three year period
 - . confirm that where the apiaries are used for production of comb honey the level of tutin in any targeted honey sample has not exceeded 0.01mg/kg
- . Box section comb honey must not be produced for sale from apiaries using this option except in years when targeted honey samples are not required to be taken
- . Targeted honey samples means a representative sample of honey from an apiary or apiaries with a common foraging area:
 - . from the last harvest of each season and
 - . harvested between 1 January and 30 June of that year
 - . records must be kept for four years from the date on which honey is packed for sale for human consumption
 - . this option is not available here honey is harvested later in the season than the last tested harvest date.

Honey (other than comb honey)

Where honey has exceeded the maximum level it must be disposed of by:

- . diluting the honey with uncontaminated honey and homogenizing and testing the honey to prove compliance with the maximum level prior to packing for sale
- . records of disposal of contaminated honey must be kept for four years from the date of disposal.

Requirements relating to sampling and testing honey (other than comb honey) to comply with option one and option five

For honey (other than comb honey) a representative sample must be taken from each batch of honey before it is put into containers for sale for human consumption

A representative sample may be taken when filling a bulk container, this may be done before the honey is mixed into a homogenous batch or by core sampling honey from a drum

The sample must be submitted for testing at an accredited laboratory using a validated testing method

The laboratory may combine samples from multiple batches for analysis if:

- asked to do so by the person seeking the test
- doing so will not compromise the test result and
- the results are reported in a way that clearly indicates whether one or more of the combined samples may have exceeded the limit./

personnel and environmental sources), which are expected to be controlled by GOP (supporting systems).

- (7) Applying these principles is discussed in detail in the RMP Manual.

7.1.7 HACCP application for products and processes not covered by this code

- (1) Carry out your own HACCP application if the one given in this document does not adequately cover your product or process. Use the HACCP approach and format shown here as a guide or pattern for your own application.
- (2) This Code covers the following processes for HACCP:
 - a) extraction of honey;
 - b) processing of liquid and creamed honey; and
 - c) processing of pollen.
- (3) The HACCP application must be documented, and supported using information such as historical company records, technical publications or information provided by MPI [RMP Spec 9].
- (4) The person or people involved in this activity must have the appropriate knowledge and skills regarding HACCP, the product and the process [RMP Spec 15 (1)].

7.2 HACCP application for the extraction, processing and packaging of honey

7.2.1 Scope

Guidance Table 6: Scope of the HACCP application

Components	Description/Details
Material being processed	Blossom honey or honeydew honey
Products	• Liquid honey¹ • Creamed honey² • Comb honey³ • Bulk honey⁴ • Wax
Process	• From receipt of supers to dispatch of packed honey • Key processing operations: – Extraction⁵ – Processing of liquid or creamed honey (including heating, straining, creaming, blending) – Cutting of comb honey – Packing – Storage

1. Liquid honey is extracted honey that has been processed to make it completely liquid and free from visible crystals.

2. Creamed honey is extracted honey that has been processed by controlled crystallization.

3. Comb honey is honey presented in its original comb or portions thereof.

4. Bulk honey is the common term used in New Zealand for honey obtained by extraction, settling or straining, and with or without minimal heating. Bulk honey is usually packed in drums or IBCs.

5. Extraction is the removal of honey from the comb by centrifugal force, gravity, crushing, straining or other means.

7.2.2 Product description

Guidance Table 7: Intended use and consumer of products and product requirements

Product	Liquid or creamed honey	Comb honey	Bulk honey	Wax
Intended consumer	Humans (general public)	Humans (general public)	Humans (general public)	Humans (general public)
Intended use of product that leaves RMP ^{1, 2}	Ready-to-eat Ingredient for preparation of other foods	Ready-to-eat	Further processing and packing to liquid/creamed honey or other honey products Ingredient for preparation of other foods	Further processing into products for pharmaceutical use and manufacture of cosmetics, etc. Further processing into comb foundation Applying as a coating on plastic frames
Regulatory limits ³	Food Standards Code 1.4.1 Sch 19-6 – Tutin 0.7mg/kg	<u>Food Standard: Tutin in Honey 2016</u> Tutin 0.01mg/kg	Food Standards Code 1.4.1 Sch 19-6 – Tutin 0.7mg/kg	None
Other regulatory requirements specific to honey	Food Standards Code 2.8.2 - Reducing sugars ≥ 60% Moisture ≤ 21%	Food Standards Code 2.8.2 - Reducing sugars ≥ 60% Moisture ≤ 21%	Food Standards Code 2.8.2 - Reducing sugars ≥ 60% Moisture ≤ 21%	N/A
	Animal Products Notice: Contaminant Specifications 2016 Specified chemical substances in honey ≤ maximum permissible levels ⁴	Animal Products Notice: Contaminant Specifications 2016 Specified chemical substances in honey ≤ maximum permissible levels ⁴	Animal Products Notice: Contaminant Specifications 2016 Specified chemical substances in honey ≤ maximum permissible levels ⁴	N/A
Labelling	Labelling of retail packs as specified in the Food Standards Code. Labelling of transportation outers <u>Part 6.6</u> of this Code.	Labelling of retail packs as specified in the Food Standards Code. Labelling of transportation outers <u>Part 6.6</u> of this Code.	Labelling of transportation outers <u>Part 6.6</u> of this Code.	Labelling of transportation outers <u>Part 6.6</u> of this Code.

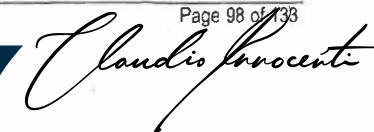
1. It is common practice in the New Zealand honey industry to downgrade honey that does not meet certain commercial requirements (e.g. burnt, fermented honey) for animal consumption (e.g. fed to bees or used for stock feed).

2. Wax may also be further processed into products that are not for human or animal consumption (e.g. candles, floor wax, furniture wax).

3. Regulatory limits are limits that are essential to be met for food safety and are established by MPI under the APA and Food Standards Code.

4. Every consignment of honey must be provided with a Harvest Declaration as required by clause 5(1) of Animal Products (Harvest Statement and Tulin Requirements for Export Bee Products) Notice 2010. This statement confirms the controls applied by the beekeeper that are intended to minimise the risks to human health from agricultural chemicals (e.g. pesticides, herbicides) and plant toxins, including tulin.

Note: Where the operator is exporting, additional labelling requirements may be described within the export requirements (OMARs).



7.2.4 Hazard analysis and CCP determination

7.2.4.1 Identification of hazards from inputs

(1) Hazards associated with each input are identified, considering any supplier agreements and requirements given in the Code.

Guidance Table 8: Hazard identification

Inputs	Description/specification	Biological hazard (B)	Chemical hazard (C)	Physical hazard (P)
Honey supers ¹	Accompanied by a Harvest declaration)	Bacterial spores (e.g. <i>Bacillus</i> spp., <i>Clostridium</i> spp.) ²	Plant toxins (e.g. tutin) ³ Chemical residues (e.g. varroacides, herbicides, pesticides) ⁴	Wire, wood, and nails from wooden frames Plastic from plastic frames
Starter honey	Produced under an RMP (may be own product or purchased from another supplier)	Bacterial spores (e.g. <i>Bacillus</i> spp., <i>Clostridium</i> spp.)	Plant toxins (e.g. tutin) ³ Chemical residues (e.g. varroacides, herbicides, pesticides) ⁴	None
Drums	Meets the drum requirements given in 6.3 Packaging of this Code.	None	None	None
Plastic containers	Suitable for use as food contact material as specified in 6.3 Packaging of this Code.	None	None	Plastic pieces
Glass jars	Suitable for use as food contact material as specified in 6.3 Packaging of this Code.	None	None	Glass fragments

1. Generally, only new foundations and combs are used for producing comb honey.

2. The pathogenic microorganisms of concern in honey are primarily spore-forming bacteria. Bacterial spores, particularly those in the *Bacillus* genus, are regularly found in honey. *Clostridium* spores, such as *Clostridium perfringens*, can also be found in honey. Microorganisms can be introduced into honey either while the bees are making the honey (known as the primary source) or after the honey has been harvested (a secondary source). The primary sources of microorganisms are likely to include pollen, the digestive tracts of honey bees, dust, dirt, and flowers.

3. There have been a number of reported cases of tutin poisoning in New Zealand. Tutin toxicity in honey results from honey bees gathering honeydew exudate from the sap-sucking insect commonly known as the passion vine hopper, when these vine hoppers have been feeding on the sap of tutu (*C. arborea*, *C. sarmentosa*) bushes. Certain beekeeper controls and the use of the Harvest declaration are intended to minimise the risk to human health from tutin in honey. Beekeeper controls include: removing hives and honey supers before the risk period; or by monitoring the tutu, vine hopper and foraging conditions in the areas around the apiary and not collecting honey when conditions indicate that tutin is likely to be a problem.

Comb honey poses a greater risk to human health from tutin because it is eaten directly off the comb, increasing the chance of consuming honey with a high concentration of tutin. Extracted honey is often bulked or blended with other honey thereby reducing the concentration of toxin.

4. The types of chemical residues that can occur in honey include pesticides for controlling mites and insect infestations, varroacides, herbicides and fungicides. The control of chemical residues involves effective beekeeping practices (confirmed by the Harvest Declaration) and the monitoring of certain chemical residues.

7.2.4.2 Process step hazard analysis and CCP determination

Guidance Table 9: Hazard analysis and CCP determination for the extraction of honey

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2. If no, consider hazard at next step.	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit? If yes, this step is a CCP. If no, this step is not a CCP.	CCP no.
1. Receiving	Supers	B – Bacterial pathogens	Bacterial spores (e.g. <i>Bacillus</i> spp, <i>Clostridium</i> spp) may occur	No	No	
		C – Tutin toxin	Reported incidence of tutin in NZ honey	Yes – Harvest Declarations confirming beekeeper controls and options 1-5 ¹	Yes	1
		C – Chemical residues	Residues may occur in honey e.g. natural, weed killers, etc. ²	Yes – Harvest Declarations confirming beekeeper controls	No	
2. Holding in hot room/storeroom	Supers	B – Bacterial pathogens	Hazard carried over from previous step	No		
3. Deboxing	Supers	B – Bacterial pathogens	Micro contamination from boxes (e.g. dirt, insect larvae, rodent excretions) can occur	Yes – GOP: visual inspection of combs; removal of defective and infested combs; and hygienic practices will minimise contamination	No	
4. Uncapping	Combs	B – Bacterial pathogens	Micro contamination from the cappings (e.g. dirt, dust, dead bees, brood, pollen and other foreign matter) is likely to occur	Yes – GOP: hygienic practices; and maintenance of uncapping knife will minimise contamination	No	

7.2.4.2 Process step hazard analysis and CCP determination

Guidance Table 9: Hazard analysis and CCP determination for the extraction of honey

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2. If no, consider hazard at next step.	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit? If yes, this step is a CCP. If no, this step is not a CCP.	CCP no.
1. Receiving	Supers	B – Bacterial pathogens	Bacterial spores (e.g. <i>Bacillus</i> spp, <i>Clostridium</i> spp) may occur	No	No	
		C – Tutin toxin	Reported incidence of tutin in NZ honey	Yes – Harvest Declarations confirming beekeeper controls and options 1-5 ¹	Yes	1
		C – Chemical residues	Residues may occur in honey e.g. natural, weed killers, etc. ²	Yes – Harvest Declarations confirming beekeeper controls	No	
2. Holding in hot room/storeroom	Supers	B – Bacterial pathogens	Hazard carried over from previous step	No		
3. Deboxing	Supers	B – Bacterial pathogens	Micro contamination from boxes (e.g. dirt, insect larvae, rodent excretions) can occur	Yes – GOP: visual inspection of combs; removal of defective and infested combs; and hygienic practices will minimise contamination	No	
4. Uncapping	Combs	B – Bacterial pathogens	Micro contamination from the cappings (e.g. dirt, dust, dead bees, brood, pollen and other foreign matter) is likely to occur	Yes – GOP: hygienic practices; and maintenance of uncapping knife will minimise contamination	No	

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2. If no, consider hazard at next step.	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit? If yes, this step is a CCP. If no, this step is not a CCP.	CCP no.
5. Pricking /loosening	Combs – uncapped – capped	B – Bacterial pathogens	Micro contamination from the pricker/loosener can occur	Yes – GOP: cleaning of pricker/loosener will minimise contamination	No	
6. Extraction	Uncapped or pricked combs	B – Bacterial pathogens	Micro contamination from the comb and frames is likely to occur	Yes – GOP: removal of damaged and dirty combs/frames; and cleaning and maintenance of equipment will minimise contamination	No	
		P – Foreign objects, e.g. wood, wire, nails, plastic	Wood pieces, wire fragments and nails from wooden frames, and plastic from plastic frames can occur	Yes – GOP: maintenance of frames will minimise the hazards Straining of honey	No	
7. Sump	Extracted honey	B – Bacterial pathogens	Micro contamination from the sump and surroundings can occur	Yes – GOP: cleaning of sump; regular removal of debris; and covering of sump will minimise contamination	No	
		P – Foreign objects, e.g. wood, wire, nails, plastic	Carried over from previous step	Yes – GOP: removal of debris from the sump will remove some physical hazards	No	
	Honey separated from cappings	B – Bacterial pathogens	Honey separated from cappings can have higher micro levels.	Yes – Excluding honey from cappings will minimise micro contamination of honey	No	
8. Heating	Extracted honey	B – Bacterial pathogens	Carried over from previous step	No		

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2. If no, consider hazard at next step.	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit? If yes, this step is a CCP. If no, this step is not a CCP.	CCP no.
		P – Foreign objects, e.g. wood, wire, nails, plastic	Carried over from previous step	No		
9. Spinning	Extracted honey	B – Bacterial pathogens	Carried over from previous step	No		
		P – Foreign objects, e.g. wood, wire, nails, plastic	Carried over from previous step	Yes – GOP: most physical hazards are removed when honey is passed through the spinner	No	
10. Pumping into tanks & straining/filtering	Extracted honey	B – Bacterial pathogens	Carried over from previous step	No		
		P – Foreign objects, e.g. wood, wire, nails, plastic	Carried over from previous step	Yes – GOP: any remaining physical hazards are removed by the strainer/filter ³	No	
11. Holding in tanks	Extracted honey	B – Bacterial pathogens	Carried over from previous step	No		
12. Filling into drums & weighing	Extracted honey	B – Bacterial pathogens	Carried over from previous step	No		
	Drums	B – Bacterial pathogens	Micro contamination from left over honey or other food residue can occur.	Yes – GOP: compliance with drum requirements; and cleaning of drums will minimise contamination	No	
		C – Chemical residues	Chemical residues from reused drums can occur.	Yes – GOP: compliance with drum requirements	No	

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2. If no, consider hazard at next step.	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit? If yes, this step is a CCP. If no, this step is not a CCP.	CCP no.
13. Labelling/ marking of drums	Bulk honey	B – Bacterial pathogens	Carried over from previous step	No		
14. Storage	Bulk honey	B – Bacterial pathogens	Carried over from previous step	No		
15. Dispatch	Bulk honey	B – Bacterial pathogens	Carried over from previous step ⁴	No		
		C – Tutin toxin	Carried over from step 1 <0.7mg/kg	No	No	
		C – Chemical residues	Residues may occur in honey ²	No	No	

1. The Food Standard: Tutin in Honey 2016 describes 5 options for managing tutin in honey to ensure tutin level <0.7mg/kg.

2. Chemical residues can occur when beekeepers or farmers use agricultural chemicals and veterinary medicines in and around hives. Beekeepers must follow all product label directions when directly treating hives and work to minimise bee's exposure to pastures sprayed with agricultural chemicals while honey supers are on their hives. If beekeepers inform you of any potential concerns regarding chemical exposure of bees or honey supers, or declare a known or suspected exposure, defer extracting the affected supers and contact your verification agency or MPI for advice.

3. If the operation has no steps for removing foreign matter (e.g. spinner or other strainer device), bulk honey produced from this operation is likely to contain foreign matter, including objects that may be considered as physical hazards (e.g. wire, stones). The operator who will further process or pack the bulk honey must ensure that these hazards are eliminated by their process [RMP Spec 11 (1)].

4. Vegetative forms of bacterial pathogens (e.g. *Salmonella* spp., *Listeria monocytogenes*) have not been detected in honey. However, bacterial spores (e.g. *Bacillus* spp, *Clostridium* spp) may occur in honey. Although these spores will not grow in honey, when it is used as an ingredient in another food, the bacterial spores from honey could be introduced to and grow in that food.

Guidance Table 10: Hazard analysis and CCP determination for the processing of liquid and creamed honey

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2. If no, consider hazard at next step.	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit? If yes, this step is a CCP. If no, this step is not a CCP.	CCP no.
1. Receiving	Bulk honey ¹	B – Bacterial pathogens	Bacterial spores (e.g. <i>B. cereus</i> , <i>Clostridium</i> spp) may occur in honey	No		
		C – Tutin toxin	Reported incidence of tutin in NZ honey	Yes – Harvest Declarations confirming beekeeper controls and options 1-5 ²	Yes	1
		C – Chemical residues	Residues may occur in honey ³	Yes – Harvest Declarations confirming beekeeper controls	No	
2. Cleaning of drum external surface	Bulk honey	B – Bacterial pathogens	Carried over from previous step.	No		
3. Heating in hot room	Bulk honey	B – Bacterial pathogens	Carried over from previous step.	No		
4. Transfer of honey into vats/tanks & straining	Bulk honey	B – Bacterial pathogens	Micro contamination from equipment can occur	Yes – GOP: hygienic practices and cleaning of equipment will minimise contamination	No	
5. Heating using heat exchanger	Honey	B – Bacterial pathogens	Carried over from previous step	No		
6. Filtering	Honey	B – Bacterial pathogens	Carried over from previous step	No		
7. Creaming	Honey	B – Bacterial pathogens	Micro contamination from equipment can occur	Yes – GOP: hygienic practices and cleaning of equipment will minimise contamination	No	

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2. If no, consider hazard at next step.	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit? If yes, this step is a CCP. If no, this step is not a CCP.	CCP no.
	Starter honey	B – Bacterial pathogens	Bacterial spores (e.g. <i>B. cereus</i> , <i>Clostridium</i> spp) may occur in honey	No		
8. Holding in tanks	Liquid or creamed honey	B – Bacterial pathogens	Micro contamination from equipment can occur	Yes – GOP: hygienic practices and cleaning of tanks will minimise contamination	No	
9. Packing and labelling	Honey	B – Bacterial pathogens	Carried over from previous step	No		
	Glass jars & lids	Glass	Pieces of broken glass are occasionally found in glass consignments; jars can also break during handling and processing	Yes – GOP: supplier agreement; visual inspection; correct handling procedures; and proper setting of machines will prevent contamination	No	
	Plastic containers	Plastic pieces	Plastic pieces are occasionally found in container consignments	Yes – GOP: supplier agreement; visual inspection; and correct handling procedures will prevent contamination	No	
10. Storage	Packed honey	B – Bacterial pathogens	Carried over from previous step	No		
11. Dispatch	Packed honey	B – Bacterial pathogens	Carried over from previous step ⁴	No		
		C – Tutin toxin	Carried over from step 1 <0.7mg/kg	No	No	

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2. If no, consider hazard at next step.	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit? If yes, this step is a CCP. If no, this step is not a CCP.	CCP no.
		C – Chemical residues	Residues may occur in honey ³	No	No	

1. It is assumed in this hazard analysis that the bulk honey received has undergone a process which has eliminated any physical hazards (e.g. by straining). Bulk honey that has not undergone effective spinning and/or straining after extraction is likely to contain foreign matter, including objects that may be considered as physical hazards (e.g. wire, stones). The operator who will further process or pack this type of bulk honey must ensure that the relevant physical hazards are identified in their hazard analysis and controlled by their process (e.g. by filtering) [RMP Spec 11 (1)].

2. The Food Standard: Tuten in Honey 2016 describes 5 options for managing tuten in honey to ensure tuten level <0.7mg/kg.

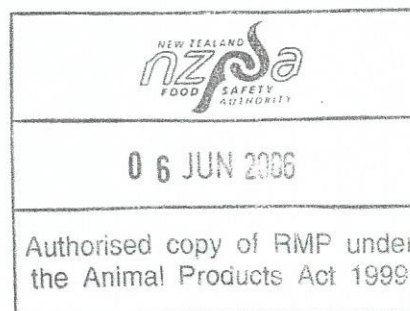
3. Chemical residues can occur when beekeepers or farmers use agricultural chemicals and veterinary medicines in and around hives. Beekeepers must follow all product label directions when directly treating hives and work to minimise bee's exposure to pastures sprayed with agricultural chemicals while honey supers are on their hives. If beekeepers inform you of any potential concerns regarding chemical exposure of bees or honey supers, or declare a known or suspected exposure, defer extracting the affected supers and contact your verification agency or MPI for advice.

4. Vegetative forms of bacterial pathogens (e.g. *Listeria monocytogenes*) have not been detected in honey. However, bacterial spores (e.g. *Bacillus* spp, *Clostridium* spp) may occur in honey. Although these spores will not grow in honey, when it is used as an ingredient in another food, the bacterial spores from honey could be introduced to and grow in that food.

5 RMP Template for the Processing of Honey and Dried Pollen

This RMP template applies to businesses that are involved in the processing of honey or dried pollen.
The *Guidelines for Completing the RMP Template* should be referred to when completing this template.

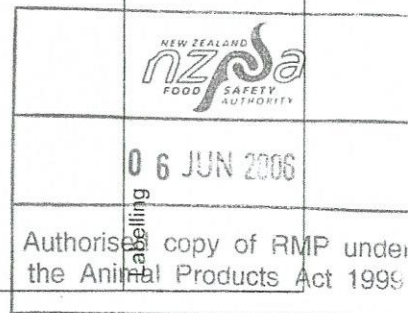
The RMP template starts on the next page. This page is not part of the RMP.



1. Business Identification											
Business ID: <u>BI I</u>	RMP No.: <u>01 B13</u>										
2. Operator Name, Business Address and Contact Details											
Full legal name (Company, sole trader, partnership): <u>David & Christine West.</u>											
Trading name (if different): <u>Bees Inn.</u>											
Physical address(es) of premises: <u>27 West Rd.</u> <u>Chaupe.</u>	Phone No: <u>(07) 8236 513</u> Fax No: <u>(07) 8236 563</u> E-mail: <u>dave-west@extra.co.nz</u>										
Postal address (for communication): <u>NZ Post Centre</u> <u>Chaupe.</u>	☒ I give consent to being provided electronic information.										
3. Responsible Person											
Role	Name, position or designation	Contact Details (if different from above)									
Day-to-day Manager of the RMP	<u>Plant Manager.</u>	<u>Same as above.</u>									
4. Scope of the RMP											
☐ The physical boundaries of the RMP are shown on the attached site plan.											
The RMP covers the following processes or activities: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> ☒ Extraction of honey ☒ Processing and packing of liquid or creamed honey ☐ Cutting and packing of comb honey ☒ Storage of honey </td> <td style="width: 50%; vertical-align: top;"> ☒ Melting and moulding of bees wax ☐ Drying, cleaning and packing of dried pollen ☐ Other (specify) _____ </td> </tr> </table>			☒ Extraction of honey ☒ Processing and packing of liquid or creamed honey ☐ Cutting and packing of comb honey ☒ Storage of honey	☒ Melting and moulding of bees wax ☐ Drying, cleaning and packing of dried pollen ☐ Other (specify) _____							
☒ Extraction of honey ☒ Processing and packing of liquid or creamed honey ☐ Cutting and packing of comb honey ☒ Storage of honey	☒ Melting and moulding of bees wax ☐ Drying, cleaning and packing of dried pollen ☐ Other (specify) _____										
The following products or activities that occur within the physical boundaries of the RMP are excluded because they are covered under a different RMP or under the Food Act : <table style="width: 100%; border: none; margin-top: 10px;"> <tr> <td style="width: 30%;">Product or activity:</td> <td style="width: 30%;">Covered under:</td> <td style="width: 40%;"></td> </tr> <tr> <td>_____</td> <td>☐ Another RMP No. _____</td> <td>☐ Food Act</td> </tr> <tr> <td>_____</td> <td>☐ Another RMP No. _____</td> <td>☐ Food Act</td> </tr> </table>			Product or activity:	Covered under:		_____	☐ Another RMP No. _____	☐ Food Act	_____	☐ Another RMP No. _____	☐ Food Act
Product or activity:	Covered under:										
_____	☐ Another RMP No. _____	☐ Food Act									
_____	☐ Another RMP No. _____	☐ Food Act									

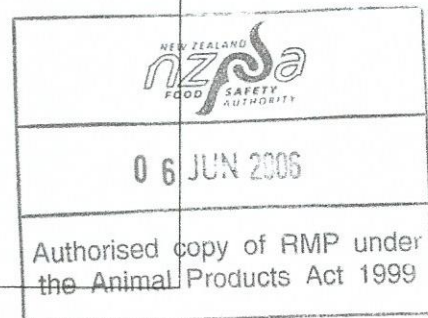

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5. Product Description			
Products	Bulk honey	Liquid or creamed honey	Comb honey
Intended consumer	Humans (general public)	Humans (general public)	Humans (general public)
Intended use of product that leaves RMP	- Further processing and packing to liquid/creamed honey or other honey products - Ingredient for preparation of other foods	- Ready-to-eat - Ingredient for preparation of other foods	- Ready-to-eat - Ingredient for preparation of other foods
Regulatory limits	None	None	None
Other regulatory requirements specific to product	Food Standards Code 2.8.2 - - Reducing sugars $\geq 60\%$ - Moisture $\leq 21\%$	Food Standards Code 2.8.2 - - Reducing sugars $\geq 60\%$ - Moisture $\leq 21\%$	Food Standards Code 2.8.2 - - Reducing sugars $\geq 60\%$ - Moisture $\leq 21\%$
	AP (Residue Specification) Notice 2004 - Specified chemical substances in honey $\leq$ maximum permissible levels	AP (Residue Specification) Notice 2004 - Specified chemical substances in honey $\leq$ maximum permissible levels	AP (Residue Specification) Notice 2004 - Specified chemical substances in honey $\leq$ maximum permissible levels
	Every consignment of honey must be provided with an <i>Apiarist and Beekeeper Statement</i> (i.e. Harvest declaration) and comply with HC Spec 108.	Every consignment of honey must be provided with an <i>Apiarist and Beekeeper Statement</i> (i.e. Harvest declaration) and comply with HC Spec 108.	Every consignment of honey must be provided with an <i>Apiarist and Beekeeper Statement</i> (i.e. Harvest declaration) and comply with HC Spec 108.
	Labelling of transportation outers as specified in HC Spec 32.	Labelling of retail packs as specified in the Food Standards Code. Labelling of transportation outers as specified in HC Spec 32.	Labelling of retail packs as specified in the Food Standards Code. Labelling of transportation outers as specified in HC Spec 32.



5. Product Description (continued)

Products	Beeswax	Spilt honey, downgraded honey (e.g. fermented)	Dried pollen	Others
Intended consumer	Humans (general public)	Animals	Humans (general public)	
Intended use of product that leaves RMP	- Further processing into products for pharmaceutical use and manufacture of cosmetics - Further processing into comb foundation	Feed for bees and other animals (e.g. horses).	- Ready-to-eat - Ingredient for preparation of other foods & dietary supplements	
Regulatory limits	None	None	None	
Other regulatory requirements specific to product	N/A	N/A	Every consignment of pollen must be provided with an <i>Apiarist and Beekeeper Statement</i> and comply with HC Spec 108.	
Labelling	Labelling of transportation outers as specified in HC Spec 32.	Labelled "Not for Human Consumption"	- Labelling of retail packs as specified in the Food Standards Code including an advisory statement as required by Standard 1.2.3. - Labelling of transportation outers as specified in HC Spec 32.	



6. Process Description			
Bulk honey	Liquid or creamed honey	Comb honey	Beeswax
☒ Receiving supers ☒ Holding in hot room/store room ☒ Deboxing ☒ Uncapping ☒ Pricking/loosening ☒ Extraction ☒ Transfer through sump ☒ Heating using heat exchanger ☒ Spinning & Straining ☒ Pumping into tanks & Drums ☒ straining	☒ Receiving of bulk honey ☒ Storage ☒ Cleaning drum external surface ☒ Heating in hot room ☒ Pouring honey into vats/tanks ☒ Heating using heat exchanger ☒ Filtering ☒ Creaming ☒ Holding in tanks ☒ Packing and labelling ☒ Storage ☒ Dispatch	☐ Receiving of honey supers ☐ Storage of supers ☐ Deboxing ☐ Removal of wires ☐ Inspection of combs ☐ Cutting of combs ☐ Packing & labelling ☐ Freezing ☐ Dispatch	☒ Collection of cappings and other wax material ☒ Separation of honey from cappings ☒ Melting of wax ☒ Filling of wax into moulds ☒ Cooling ☒ Dispatch

Holding in tanks	
Filling of honey into drums	
Labelling/marketing of drums	
Storage	
Dispatch	6 JUN 2006 Authorised copy of RMP under the Animal Products Act 1999

6. Process Description (continued)	
Dried pollen	Others
☐ Receiving-pollen-	
☐ Holding in freezer	
☐ Drying	
☐ Cleaning and sorting	
☐ Bulk packing	
☐ Retail packing & labelling	
☐ Storage	
☐ Dispatch	

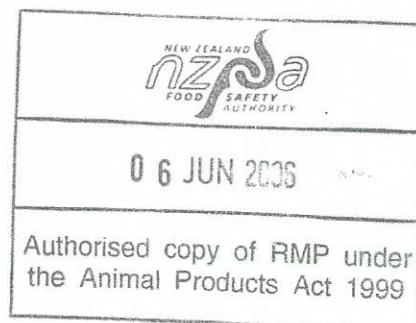
	
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7. External Verification**Verifier's Freedom and Access to carry out Verification Functions (RMP Specifications 2003, clause 15)**

I authorise my contracted verifier to have the freedom and access necessary to allow him/her to carry out verification functions and activities, including —

- (a) having access to all parts of the premises or place and facilities within the physical boundaries of, or relating to, the risk management programme; and
- (b) having access to all documentation, records and information relating to, or comprising, the risk management programme (including records held in electronic or other form); and
- (c) having freedom to examine all things necessary and open any containers, packages and other associated things to inspect their contents; and
- (d) having freedom to identify or mark any animal material, animal product, equipment, package, container or other associated thing; and
- (e) having freedom to—
 - (i) examine and take samples of any animal material, animal product or any other input, substance, or associated thing which has been, is, or may be in contact with, or in the vicinity of, any animal material or animal product; and
 - (ii) test, or analyse, or arrange for the testing or analysis of such samples; and
 - (iii) order retention of materials including animal material, ingredients, animal product, packaging or equipment pending testing results and decisions on disposition; and
- (f) having authority to detain any animal material and animal product or other relevant things in the event of non-compliance with the risk management programme where there may be significant risk to fitness for intended purpose of animal product or suitability for processing of animal material; and
- (g) having authority to intervene and direct a temporary interruption of processing in cases of significant risk to fitness for intended purpose of animal product or suitability of animal material for processing until the cause of the risk has been remedied.

☒ A letter has been received from the verification agency confirming they will verify the RMP at all sites covered by this RMP.



8. RMP Document List, Responsibilities For and Authorisation of RMP

Document	Documents from the COP		Operator's own documents based on the COP		Operator's own documents for additional products/processes/procedures		Person responsible for Implementation
	Reference	Date	Reference	Date	Reference	Date	
Main part of RMP (this document)	N/A		Completed RMP template				
GMP Supporting Systems: Design and construction of buildings, facilities and equipment	Part 2 Sec 2.3.1 - 2.3.4	July 01					D. West.
Potable water	Town Supply AS discussed on Page 8. Bul						
Cleaning and sanitation	Part 2, Sec 4	July 01	Cleaning Schedule				C. West.
Personnel competency, health and hygiene	Part 2 Sec 5	July 01					C. West.
Control of chemicals	Part 2 Sec 6	July 01	Approved chemicals list				C. West.
Pest control	Part 2 Sec 7	July 01	Pest Control Schedule				C. West.
Packaging materials (specifications, handling and storage)	Part 2 Sec 8	July 01					"
Receipt and processing of honey and dried pollen	Part 2 Sec 9	July 01					D. West.
Document control and record keeping (including inventory control)	Part 2 Sec 10	July 01	Inventory Control				D. West.
Recall of products	Part 2 Sec 11	15/6/06					D. West.
Operator verification	Part 2 Sec 12	July 01					D. West.



Copy of RMP under Products Act 1999

8. RMP Document List, Responsibilities For and Authorisation of RMP (continued)

Document	Documents from the COP		Operator's own documents based on the COP		Operator's own documents for additional products/processes/procedures		Person responsible for Implementation
	Reference	Date	Reference	Date	Reference	Date	
HACCP Application	Part 3.	July 05					D. West.
Identification of risk factors related to wholesomeness and labelling	Part 4.	July 05					C. West.
Other documents:							
Site plan of physical boundaries							
Letter from Verification Agency			VA letter	20/03/06			D. West.
Assessment of Water Supply Status (only necessary for own supply)	NIA Town Supply	July 05		20/03/06			C. West.
Record forms	Pre Season Check List	20-3-06	Daily log book, Cleaning Check List, Inventory forms	20/03/06			C. West.

9. Confirmation

☐ I confirm that all of the documents listed in Section 8 are appropriate for my operation.
☐ I confirm that all facilities and equipment necessary to implement the RMP are available and ready to operate.
☐ I confirm that the RMP, including all supporting systems, has been authorised by me.
☐ I confirm that the RMP will be implemented as written, including all relevant parts of the code of practice.

Authorised copy of RMP the Animal Products Act 1999
 JUN 2006
 Signature of Operator or Day-to-day Manager of RMP:

Date: 28/3/06

PROCEDURES - HYGIENIC PRACTISES TO BE FOLLOWED BEFORE ENTERING PROCESSING OR PACKING AREAS

Ensure all workers are medically fit and competent to perform their duties and comply with good hygienic practices so as to prevent or minimize the contamination of bee products, other inputs, packaging equipment and the processing environment. People entering the processing areas must comply with the hygiene routine – noncompliance will result in re-training re-cleaning, warnings.

Suitable protective clothing and footwear to be worn by workers (coats, overalls, hairnets or beard nets) which must be clean at the start of each day's operation and changed if contamination occurs while extracting or processing honey. Clean overalls/coats, hairnets, gloves to be stored separate to contaminated protective clothing.

Footwear must be waterproof and easily cleaned.

No street clothes to be worn over protective clothing.

Damaged protective clothing to be discarded if unable to be cleaned or repaired.

If changing from activities from lower to higher hygienic status:

.A complete change of protective clothing

.Washing and drying or sanitizing (where required) of the hands and arms

.Change of footwear

Foot wear must be clean and worn in processing areas only – no outside footwear to be worn in processing rooms.

All personnel must thoroughly wash and dry their hands and exposed portions of their arms with approved hand detergent and water and dry on disposable paper towels.

Hand washing should involve the following:

- . Clean under each fingernail using warm running water & soap
- . Wash hands under warm running water and approved soap, Rubbing vigorously (front and back and between fingers).
- . Dry hands thoroughly (front, back and between fingers)
- . Before entering any processing or packing areas:
- . Before handling any product or exposed packaging;
- . After using the toilet
- . After coming into contact with waste and contaminated surfaces.
- . After hand contamination from coughing, sneezing and blowing the nose.

The hand washing water in buckets is not to be used for washing contaminated hands (as above) use only for the purpose of removing sticky honey from hands. Change water in the buckets on a regular basis.

Fingernails are to be kept short and clean.
No fingernail polish is to be worn.

No drink bottles, sweets etc. in processing rooms
No spitting in processing rooms and no jewellery other than plain wedding bands (no stones) are to be worn. Ensure plain wedding bands are cleaned correctly in the same manner as for hands) and cannot be easily dislodged.

No smoking in the building.

Treat any injury, wound or cut immediately and dress with a secure waterproof dressing (coloured plaster if on hands) to prevent contamination of any product, packaging or equipment. Advise supervisor immediately.

Version 3
Created 2.4.20
JW

No worker to process honey with – acute respiratory infection, dysentery, boils, or diagnosed with an illness caused by Salmonella, Shigella spp., E. coli spp., Campylobacter, Hepatitis A virus, Covid. Advise supervisor if they are, or suspect they are suffering from any infectious disease.

Certificate from Doctor required to state worker clear before recommencing work.

No visitors to enter processing rooms handle product or enter an area where they may adversely contaminate the product if that person is suspected or confirmed to be suffering from or a carrier of an infectious disease.

All visitors to sign the visitor's book.

*Version 3
Created 2.04.20
Jm*

Claudio Innocenti

Procedures for Calibration of Measuring Equipment

- Scales to be calibrated annually by an accredited agency – Precia Molen Hamilton - or have assurance or guarantee of the instrument's accuracy provided by the equipment manufacturer
- Certificate of accuracy is to be received before use
- Calibration date and confirmation of accuracy is to be fixed to the scales by the accredited agency
- Routine in house checks of measuring equipment should be carried out at frequent intervals – 3 monthly and recorded along with the location of the measuring equipment
- Damaged or inaccurate measuring equipment to be repaired or replaced

Version 2
Created 25.06.19
Caw

IN HOUSE CALIBRATION OF SCALES AND MEASURING EQUIPMENT - Monthly

[illegible]

Version 2
Created 25.06.19
Jaw

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Procedures & Methods to Distinguish Ineligible Honey from EU-eligible Honey

1. Honey is inspected visually by taking a sample from each drum to check for moisture and aged or overheated honey.
2. Fermentation in the honey is checked by smell, first indication is a blown drum.
3. Non EU Honey is labelled as non EU and placed separately from EU Honey. Packaged EU products must be stacked separately – pallets may not be stacked vertically on top of or mixed with Non EU Honey.
Non EU Honey generally consists of scrapings off the drip trays.
4. Packed honey is placed on a pallet and batch marked etc

Non-approved chemicals to be used in amenity areas only or in the field.

No non-approved chemicals to be used in processing rooms.

Non-approved chemicals to be stored separately from approved chemicals.
Empty containers disposed of. Empty containers are **not** to be re-used for any other purpose within the premises.

If chemical contamination occurs:

Affected products should be considered unfit for human or animal consumption.

Affected contact surfaces should be cleaned and sanitised prior to re-use.

Affected packaging materials that cannot be effectively cleaned and sanitised are not to be used for packing any edible bee product.

Ensure varroa strips are not present in honey supers during the time when bees are collecting nectar and pollen.

Varroa treatments to be used according to the manufactures instructions.

Any affected product not to be used for human consumption.

Procedures for Control of Maintenance Compounds

Only MPI approved maintenance compounds to be used:

- . during processing operations
- . in maintenance of processing areas
- . in facilities and on equipment

All approved chemicals are to be stored on the approved chemical shelf, separate from non-approved chemicals and edible bee products, sealed, clearly labelled and not used for storing of food or likely to be mistaken for food.

Decanted containers of approved chemicals are to be labelled with the chemical name and directions for use in quantities needed for immediate use only.

Any product or packaging that is contaminated by a maintenance compound which adversely affects its purpose must not be used for human or animal consumption.

Register of current maintenance compounds to be kept

Personnel to be trained in correct handling and use of maintenance compounds – as per manufactures directions.

Directions for use are to be posted on the wall

Measuring containers to be labelled for **chemical use only**

Equipment and contact surfaces are to be thoroughly washed after exposure to any maintenance compound.

Empty chemical containers to be disposed of according to manufacturers instructions.

Empty containers are not to be re-used for any purpose within the premises.

2-2.

Inventory Control

Bee products are to be clearly identified at receipt, processing, storage and sale for inventory control and traceability purposes. Electronic records to be kept:

- . Name and address of supplier
- . batch number, quantity and delivery date
- . supplier status
- . production records, quantity, dates and batch numbers, starter honey, any re-packing done.
- . load in or load out checks
- . name of persons product sold to

Inventory to be maintained of all incoming honey and non-compliant products.

Identify non-compliant honey and the reason for non-compliance in the inventory.

Documentation in place to allow any finished product to be traced back to the supplier and apiaries the honey was sourced from and to the next person the honey is transferred to i.e. for further processing, packing, or storage, distributed or sold to

All outgoing products must be clearly labelled with documentation to ensure traceability of the batch

Inputs to be tracked through processing so product can be identified and isolated in the event that a problem occurs.

Procedures for Calibration of Measuring Equipment

- . Scales to be calibrated annually by an accredited agency – Precia Molen Hamilton - or have assurance or guarantee of the instrument's accuracy provided by the equipment manufacturer
- . Certificate of accuracy is to be received before use
- . Calibration date and confirmation of accuracy is to be fixed to the scales by the accredited agency
- . Routine in house checks of measuring equipment should be carried out at frequent intervals – 3 monthly and recorded along with the location of the measuring equipment
- . Damaged or inaccurate measuring equipment to be repaired or replaced

IN HOUSE CALIBRATION OF SCALES AND MEASURING EQUIPMENT - 1 YEARLY

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Claudio Procenti

Procedures for Non-complying Product and Recall

General requirements and Procedures

Ensure non-complying product is appropriately managed
Notify our RMP Officer and MPI immediately when there is a safety concern re any of the products –

Murray Reid Asure Quality
Phone 0508001122
Email: Murray.Reid@asurequality.com

MPI
Phone 0800 008383
Email: info@mpi.govt.nz

Check inventory control to determine if any other product may be affected.
Commence a product recall of the affected product if it has been released for sale (see mock recall for guidance)
Handle and store non-complying products separately from complying products:

- . to prevent contamination of other products
- . to prevent contamination of the storage environment

Non-complying products should be:

- . clearly identified
- . separated from other products
- . recorded in inventory as unavailable for load out
- . held within the premises until disposition is determined by a suitably skilled person to determine:
 - . product safety and suitability
 - . amount of product affected
 - . whether the product has been released for distribution or not
 - . whether the products can be reprocessed
 - . any instructions from MPI or RMP verifier

Keep records to demonstrate compliance with the requirements

Keep records for non-complying product:

- . inventory or list of non-complying products
- . records of assessment and disposition of non-complying products

Version 2
Created 23-06-19
Dew

1-4A

- records of recall activities including mock recalls
- inventory records
- any correspondence with verifier or MPI

Version 2
Created 28.06.19
DLW

2-4. #1

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Mock Recall Decision

Noticed a fitting missing from packing machine – noticed 13th February 2019.

Recall coordinator notified. CEO notified

Assessed as a potential choking hazard

MPI notified.

Verifier notified

Began recall plan

Suspended distribution of product – notified Mill Street Pak N Save

Collated traceability information

Confirmed Health Hazard

Confirmed product distributed to consumers

Carry out recall

Version 2
Created 28.06.19
Jew.

3-4 31

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Roles and Responsibilities

Recall Coordinator to stop all distribution of the product in question and arrange for return of product to collection point. Prepare inventory and distribution status of product showing where when and to whom and quantity sold.

Prepare batch identification.

Investigate cause of problem

Prepare response to consumers. Answer all consumer enquiries.

Set up stock reconciliation to determine cost of recall.

Handle all legal implications

Handle press releases – manage all media contact

Consult with regulatory agencies

Arrange for pick up from retailer

Arrange for credit to be given

Assist in pick up and arrange for delivery of credit notes

Version 2
Created 23.06.19
- DW

24.7.19

NOTIFICATION PROCEDURES

Operators are to advise the Director –General in writing of any change to the name, position or designation of the person responsible for the day to day management of the RMP.

Operators are to document procedures to notify the Director General of any emerging, new or exotic biological hazards or chemical hazards that come to the operator's attention in relation to the RMP.

Operators to follow notification requirements if exported honey is found to have non-compliant Tutin levels – (Animal Products Harvest Statement and Tutin Requirements for Export Products) Notice 2010

Operators to notify RMP verifier in writing of any;

- . Significant concern of the fitness for intended purpose of any bee product
- . Where the cumulative effect of minor amendments necessitates the significant amendments to the RMP
- . Where the RMP is considered no longer affective
- . Where the premises are no longer suitable for their use
- . Where anything within the physical boundary is used for additional purpose or by operators and
The RMP has not considered relevant hazards or risk factors.

Records to be kept:

- . Internal audit reports
- . Test results
- . Communication sent to MPI or verifier
- . Corrective actions

Version 2.
Created 25.06.19
aw.

PERSONAL COMPETENCIES AND TRAINING

Personnel are to have the knowledge and skills necessary to perform their assigned tasks.

RMP day to day manager – Chris West

Person who authorises all or parts of the RMP document – Chris West

Personnel involved in process control, monitoring, corrective action and operator verification – Dave & Chris West

Personnel skills & competencies are to be documented, dated and signed to enable the effective operation of the RMP. RMP records to be kept in an easily acceptable form demonstrating effective operation of the RMP

Operators must ensure the ongoing maintenance of skills of those involved in the following:

- . Process control and monitoring
- . Corrective action
- . Operator verification

New personnel are to be informed before starting work of:

- . Their job description
- . Health requirements
- . Hygienic practices and procedures.

Ongoing supervision and/or training should be provided to ensure that new personnel are trained in their specific tasks, and in hygienic practices and procedures. Review training programme annually.

Training to include:

- . Health and personal hygiene

*Version 2.6.19
Created 20.6.19
CW.*

- . Movement of personnel and materials
- . Cleaning and sanitation
- . Hygienic handling of materials and products

Hygienic practices signs – hand washing, use of protective clothing, cleaning and sanitation to be posted outside processing areas.

Visitors and contractors to report to the responsible person on arrival and be supervised by assigned staff. Hygienic practices and procedures are to be followed by the visitor or contractor – no visitor or contractor to handle edible bee product or enter processing areas unless they have complied with all the hygiene requirements for food handlers.

Visitors must sign a visitors log book and be able to declare they are free from diseases.

Version 2.
Created 20.6.19
QW.

Procedures for Labelling and Identification of Bee Products

To ensure bee products are correctly identified and labelled to meet requirements and traceability.

Products packaged for retail sale must be labelled in accordance with the Food Standards Code, Fair trading Act 1986 and Weights and Measures Act 1987

Unlabelled retail packs and bulk honey should be identified with:

- . The RMP number where the honey was packed
- . Product description – i.e. the word "honey"
- . Country of origin
- . Product's batch code

Transportation outers to have:

- . Product name
- . Storage conditions where necessary
- . Lot identification – or batch number

Any bee product that is not intended for human consumption but could be mistaken for human consumption must clearly indicate that the bee product is **not** intended for human consumption.

If the status of honey or other bee product's fitness for intended purpose changes and the product has been identified, all affected labelling or documentation (where there is no label) must be amended to reflect its new status prior to release for trade, or the packaging including labelling must be replaced.

Any false or misleading labelling on reused or recycled packaging resulting from previous uses must be removed or defaced at the consigning premises on the

- . transportation outer
- . accompanying documentation

Records to be kept:

- . Label checklists
- . Verified translations of labels'
- . Copies of labels

Version 2
Created 26.06.19
CW

PROCEDURES FOR RETAIL PACKS						
Labels are designed to meet Regulatory requirements	Yes	26.06.19				ew
All information printed on labels or packing are correct and accurate	Yes,	✓				ew,
Any claims or product labels are accurate and evidence is available to support the claims	Yes.	✓				ew.
The correct label is applied to each product unit	Yes.	✓				ew.
Labels are stored in a manner that maintains them in good condition	Yes.	✓				ew
Damaged or obsolete labels are disposed of appropriately	Yes.	✓				ew.
Rework is identified and tracked to finished product	Yes	✓				ew.
"One step forward, one step backward" traceability is maintained; and inventory control is maintained	Yes	✓				ew
Products must be labelled in a manner that enables traceability to be maintained [HC Spec 8.2 (12)]	Yes.	✓				ew.

Version 2,
Created 26.06.19
Jaw

GENERAL REQUIREMENTS AND PROCEDURES

Operators to ensure corrective actions for any non-conformance or non-compliance include an assessment to determine the cause and extent of the problem and address:

- . Immediate restoration of control
- . Identification and disposition of any affected product
- . Prevention or recurrence of the problem
- . Identify the cause(s) of the problem and address these by corrective actions
- . Ensure corrective actions are carried out effectively and in a timely manner
- . Maintain a corrective action register including follow up checks, internal Audits etc
- . Operators to ensure compliance with requirements and procedures are regularly checked by a responsible person.
- . Time frame for corrective actions is to be set – e.g. correct a minor defect Within 6 months
- . Defect Categories are: critical, major, and minor

Version 2
Created 25.06.19
JW

J-3 B

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Corrective actions:

Problems are to be managed appropriately – restoration of control, product disposition and prevention of recurrence

Reality checks of workers performance and compliance with process control procedures, health and hygiene. Processing times and temperatures

Hygienic status of premises internal and external

Follow up all NC"s from previous audits

Version 2
Created 23.06.19
Jm.

2-38

Corrective Action Register

Machinery name

Defect categories

Corrective actions taken

Time frame for corrective actions

Restoration of control

Non compliances recorded

Pre-season checklist completed

3 monthly internal audit completed

Annual review completed

Critical

Major

Minor

yes

no

yes

no

yes

no

yes

no

Version 1
Created 25.06.19
AW

3-3B

OPERATOR VERIFICATION

To ensure the RMP continues to be effective – notify verifier of any issues as required

Document an Operator Verification system including:

General requirements and procedures

- . The activities performed and their frequency
- . Procedures or methods used and their frequency
- . Any actions taken when there is non-compliance and where the RMP is ineffective
- . Any recording and reporting requirements
- . Routine surveillance and monitoring checks – daily process controls
- . Reality checks of processing
- . Specific monitoring of process parameters
- . Product sampling results may provide evidence of how the system is working
- . General oversight and supervision of the operation
- . Identifying issues and transferring those to the corrective action system if necessary

Scheduled operator verification activities:

- . Internal audits of the whole RMP – 3 monthly and annually to be carried out by a suitably skilled person to ensure ongoing compliance with the RMP. Prompt corrective actions taken for non-compliances.

Records are to be kept of any observations made during an internal audit and corrective actions taken.

- . RMP review – annually – to consider whether there have been any significant changes – to the process, equipment, building, products, staff in positions of responsibility, verifier etc.
- . HACCP plan review – annually – to consider if there have been any changes to the process flow, inputs, outputs or possible hazards.

Version 2
Created 20.6.19.
Caw

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These 3 activities can be combined into one activity.

Corrective action system

Non-compliances are to be recorded on a register to simplify tracking of corrective and preventative actions. Identifying the root cause of defects will ensure that corrective actions are effective.

Appropriate corrective actions to regain control and prevent recurrence of the problem are to be taken. Surveillance of the system increased and a review of the RMP or GOP programme and necessary changes made.

Repetitive issues may result from:

- . Poorly maintained equipment or processing environment
- . Poor control of the process
- . Inadequately trained staff
- . Lack of resourcing
- . Lack of supervision
- . Poor standard of operator verification

Internal audits to consist of the following:

- . Person responsible for conducting the audit has auditing skills. Good understanding of the operation, processes and GOP covered by the RMP. Independence from the procedures as much as possible and a good understanding of relevant regulatory requirements
- . Audit schedule specifying when each programme is to be checked, considering seasonal activities and risk
- . Audit process
- . A review of written procedures
- . Review of records
- . Reality checks during processing
- . External audit findings
- . Confirmation that non-compliances identified from the last internal audit have been rectified

Version 2
Created 20.6.19.
ew

2-3A

. A clear description of when corrective and preventative action should be taken and what corrective and preventative action is expected

Frequency of audits is to be increased when repetitive non-compliances occur and the programme is found to be ineffective.

Internal audit procedures

Observations taken during internal audits and corrective actions taken to be recorded

Version 2
Created 20.6.19
Dev

3-3A

GENERAL REQUIREMENTS

DOCUMENT CONTROL AND RECORD KEEPING

All documents to be managed under a document control system, current & authorized. Documents are to be legible and reflect accurately the observation taken.

Obsolete documents are removed from use.

Every document that forms part of the RMP must be dated or marked to identify its version, signed by the operator and available to any person with responsibilities under the programme.

Documents such as cleaning records, pest control & transport to have the date, time recorded and signature of operator, extraction and packing records to have the date and signature recorded. Description of the results of the activity or observation recorded.

Documents are to be stored for 4 years and accessible or can be retrieved and made available within 2 working days to recognized persons.

Amendments are to be recorded on an amendment register.

Important correspondence with verifier is to be kept.

1-4c

PACKING ROOM DAILY CLEANING CHECK LIST

[illegible]

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[illegible]

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PROCEDURES FOR RETAIL PACKS						
Labels are designed to meet Regulatory requirements						
All information printed on labels or packing are correct and accurate						
Any claims or product labels are accurate and evidence is available to support the claims						
The correct label is applied to each product unit						
Labels are stored in a manner that maintains them in good condition						
Damaged or obsolete labels are disposed of appropriately						
Rework is identified and tracked to finished product						
"One step forward, one step backward" traceability is maintained; and inventory control is maintained						
Products must be labelled in a manner that enables traceability to be maintained [HC Spec 8.2 (12)]						

L6-42.

Receipt of Incoming Honey for Processing and Packaging

- . Check all Harvest Docs on receipt of honey at 'reception' – must be accurate truthful.
- . Honey must be clearly labelled and fit for purpose
- . Beekeeper supplying the honey must be listed with MPI for any export honey with official assurances – honey not to be processed without a correctly completed Harvest Doc – Tutan and signed by the beekeeper
- . Honey from unregistered beekeepers to be kept separate from export eligible honey
- . Stored in a clean dry area off the floor, away from harmful chemicals, pests, dust etc.

Packaging

- . Check packaging received intact, clean and dry and clearly labelled.
- . Supplier guarantees received
- . Stored off the floor in a clean dry area, away from chemicals, pests, dust etc and sealed
- . Packaging outers are not to be taken into processing areas
- . Damaged packaging that is not suitable for use must be disposed of
- . Part boxes of containers to be sealed when not in use and stored in a clean dry area off the floor.
- . Packaging – containers and metal drums to comply with EU and FDA Food standards codes – letters of verification to be received.
- . Drums to have tight fitting bungs – loose bungs can cause water to enter the drums – empty or full drums are to be stored in a manner that prevents the entry of water and deterioration

242.

- Re-used drums that have contained fermented honey, sucrose or glucose or orange juice are to be thoroughly washed, with potable water, dried and checked before sealing with a bung. Re checked before use
- Drums that have been used for non-food products or chemicals are not to be used for honey.
- Damaged or deteriorating drums are not to be used for honey drums

Glass jars

- Ensure metal lids are coated or lined with a food grade material suitable for honey.
- Protect glass jars during transport, dust, pests and contaminants and damage.
- Store glass jars in an inverted position. Handle glass jars carefully to prevent breakage.
- Remove broken glass and discard immediately – thoroughly check to ensure all broken pieces are removed.

3-4C.

DAILY CLEANING LIST: PACKING ROOM

1. Packing waste collected and stored in identified containers & removed from packing room at the end of each pack.
2. Floors cleaned by hosing. Water drained. Sanitized with Microdet 750B Alkaline Cleaner Sanitizer – (as below)
3. Walls cleaned with mop or wiped with clean cloths if necessary – Sanitized with Microdet 750B. 10 – 20ml / litre of water applied to soiled surfaces for 10 - 20 minutes at a temperature of 60oC.
4. Packing vats must be clean and free from honey. Clean with a clean wet cloth –inside & outside of vats sanitized with Microdet 750B (as above) and washed off. Inside of vats pre soaked in hot water & water blasted as required.
5. Packing table to be wiped down with a clean cloth & sanitized with Microdet 750B.
6. Wiping cloths must be washed daily & sanitized.
Hot water to be used for any spills on contaminated surfaces i.e. floors.
No cloths to be used on contaminated surfaces,

1-9

DAILY CLEANING CHECKLIST: EXTRACTING ROOM

1. Waste collected and stored in identified containers & removed from extracting room at the end of each day.
2. Floors cleaned by hosing with water and drained. Sanitized with Microdet 750B 10 -20ml / litres of water for 10 – 20 minutes at a temperature of 60c then washed off and drained.
3. Walls cleaned if necessary with water blaster & sanitized with Microdet as above.
4. External surfaces of all equipment including extractors & motor must be clean and free from honey and bee product residues. Clean with a clean wet cloth & hot water.
5. Dead and live bees must be removed from the extraction room.
6. Extracting room walls, uncapper and conveyor water blasted once a week or every 7 days of extracting.
7. Drain to be cleaned daily when used.
8. Water in buckets for wiping cloths must be replaced hourly. Cloths must not be used on contaminated surfaces such as the floor and must be washed daily & sanitized.
9. Electrical cables above pricker to be clean & free from cobwebs.

End of Season Cleaning and off Season Maintenance Procedure

1. Clean facilities, walls, floor, ceiling, windows, doors, light fixtures, fans, taps, and hoses so they are clean and free of honey and bee products residues.
2. Disassemble equipment as necessary and clean thoroughly by washing and dry to ensure no honey residue that may attract pests and mould.
3. No items contaminated with soil, chemicals or organic matter are to be stored in processing rooms or any other material that could leave residual contaminates after the pre-season check.
4. External areas are to be tidy with no accumulated junk to attract pests.

Version 2
Created
24.06.19
CW

[illegible]

[illegible]

[illegible]

Claudio Procenti

3 Monthly

Operator Verification

[illegible]

Date:

Date:	
Date:	
Date:	
Date:	
Date:	
Date:	

Claudio Procenti

Internal Audit

3 Monthly

Document Control Operator Verification

	Effective Control						Checked By	Date
NZFA Updates								
Pre Season Checklist								
Internal Audits								
Amendments								
Tracability of honey								
Export Certificates								
Inventory								
Drum Log								

Support Programme to be Changed

Date:	
Date:	
Date:	
Date:	
Date:	
Date:	
Date:	
Date:	

Internal Audit

3 Monthly

Receipt & Processing

Operator Verification

	Received in	Received in	Received in	Received in	Effective Control	Checked By	Date
Transfer Statements papers received							
Harvest Documents received							
Traceability Documents received							

Support Programme to be Changed

Date:	
Date:	
Date:	
Date:	
Date:	
Date:	
Date:	
Date:	

Internal Audit 3 Monthly

Potable Water

	Tested by:	Effective Control	Checked By	Date
town water				
Tested				
Results				

Annual Review or Support Programme to be changed

Date:
Date:
Date:
Date:
Date:
Date:
Date:
Date:

3 Monthly

3 Monthly

[illegible]

Annual Review or Support Programme to be changed

Date:
Date:
Date:
Date:
Date:
Date:

Claudio Procenti

Internal Audit 3 Monthly

Packaging Materials - Verification Letters Received

Packaging Materials	Company	Company	Company	Effective Control	Checked By	Date
Drums	Auckland Drum Co					
Drums	NZ Drum Co					
Honey Containers	Pharmapac					
Honey Containers	Amcor - Comag					

Support programme to be changed

Date:	
Date:	
Date:	
Date:	
Date:	
Date:	
Date:	
Date:	

Internal Audit

3 Monthly

Recalls - Batch Numbers

	Effective Control					Checked By	Date
Batch Number							
Product Recovery							
Product Disposition							
Corrective & Preventive Action							
Documentation & Communication on recall							
Review of recall							

Support Programme to be Changed

Date:	
Date:	
Date:	
Date:	

Claudio Innocenti

Internal Audit 3 Monthly

Design Constonction & Maintenance of Building Facilities & Equipment

			Effective Control	Checked By	Date
Floors, Ceiling, walls sound & easily cleaned & sanitized					
Separate Storage of Chemicals					
Lighting - approved safety type					
packaging plant in working order & stainless steel					
Extracting plant in working order & meeting standard					

Support Programme to be Changed

Date:	
Date:	
Date:	
Date:	
Date:	
Date:	
Date:	

Annual RMP review checklist

Date: ____ / ____ / ____

Present: _____

Items of Discussion		Item Addressed (☐ / ☐)	Comments (if any)
Management Issues			
1	Review of RMP contact details with regulator and verifier.		
2	Inclusion of all new products to RMP		
3	Inclusion of all new processes to RMP		
4	Review of last RMP audit findings		
5	Review of last internal audit findings		
6	Review of corrective actions reports		
7	Review of customer complaint reports (If any).		
8	Review of recall reports (if any)		
9	Review of Management verification procedure (internal audit and RMP review)		

Reference: (Enter Company Name) : COP 12 Operator Verification

Issue 1: (Enter Approval date)

Page 1 of 2

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Items of Discussion	Item Addressed (☐ / ☐)	Comments (if any)
10		
Review of Current requirements of:		
Code of Practice (COP)		
Official Assurance Programme (OAP)		
Food (Tutin in Honey) Standard 2010		
European Union Overseas Market Access Requirements (EU OMAR)		
Animal Products (Transport of Export Animal Products and Handling at point of Export) Notice 2009		
Operator's own documents review		
11		
Review of current Operator's own supportive documents including:		
Procedures, schedules		
Site plans		
Lists		
Recording forms		

Verified by: _____

Date: _____

Reference: (Enter Company Name) : COP 12 Operator Verification

Issue 1: (Enter Approval date)

Page 2 of 2

Annual RMP review checklist

Date: ____ / ____ / ____

Present: _____

Items of Discussion		Item Addressed (☐ / ☐)	Comments (if any)
Management Issues			
1	Review of RMP contact details with regulator and verifier.		
2	Inclusion of all new products to RMP		
3	Inclusion of all new processes to RMP		
4	Review of last RMP audit findings		
5	Review of last internal audit findings		
6	Review of corrective actions reports		
7	Review of customer complaint reports (if any).		
8	Review of recall reports (if any)		
9	Review of Management verification procedure (internal audit and RMP review)		

Reference: (Enter Company Name) : COP 12 Operator Verification

Issue 1: (Enter Approval date)

Page 1 of 2

Items of Discussion		Item Addressed (☐ / ☒)	Comments (if any)
10	Review of Current requirements of:		
	Code of Practice (COP)		
	Official Assurance Programme (OAP)		
	Food (Tutin in Honey) Standard 2010		
	European Union Overseas Market Access Requirements (EU OMAR)		
	Animal Products (Transport of Export Animal Products and Handling at point of Export) Notice 2009		
Operator's own documents review			
11	Review of current Operator's own supportive documents including:		
	Procedures, schedules		
	Site plans		
	Lists		
	Recording forms		

Verified by: _____

Date: _____

Reference: (Enter Company Name) : COP 12 Operator Verification

Issue 1: (Enter Approval date)

Page 2 of 2

Recall Hazard/Risk Analysis Form

Using this Form:

The decision to recall can be somewhat subjective at times. There are some situations where the hazard is known to be potentially life threatening, and the decision to recall is clear. In other situations it may be necessary to separate public perception of risk from scientific analysis of risk, and the decision to recall can be more difficult. This form is designed to clarify the thought process when making a decision to recall, and to provide a record of recall decisions for future reference.

DATE NOTIFIED	
BRAND/PRODUCT NAME	
COMPANY CONTACT DETAILS Address, email and phone details	
CONTACT PERSON Name, position, email and phone details	
PRODUCT INFORMATION	
What batch or batches is suspected?	
Are batches before and after suspected / affected?	Please tick one below: ☐ Yes ☐ No If YES what batches?
Quantity of product per batch including quantity of individual consumer packs per batch	
Product weight/volume	
Batch identification details i.e. date mark/batch code or ID as is stated on product label	
DETAILS OF HAZARD/NON COMPLIANCE (PLEASE TICK ONE BELOW) ☐ Microbiological Contamination ☐ Chemical contamination ☐ Foreign Matter ☐ Undeclared Allergen ☐ Labelling Incorrect ☐ Other	DESCRIBE HAZARD/NON COMPLIANCE
Has any testing been done?	Please tick one below: ☐ Yes ☐ No If YES please attach a copy of the test results
Does the product contravene a regulatory limit or standard?	Please tick one below: ☐ Yes ☐ No If YES which regulatory limit or standard?
Does the hazard/non-compliance have the potential to cause risk to health? Please tick one below: ☐ Yes - recall possible, proceed with risk analysis ☐ No - recall not required, unless other factors indicate otherwise (see ANY OTHER RELEVANT FACTORS). Company's own commercial risk to recall or not. Corrective action to prevent reoccurrence to be undertaken and documented.	

DISTRIBUTION DATA (see Note 2)

Where is the affected product
(batch/batches)?

Is ALL product still in company/distribution control (not yet with consumers)? Please tick one below:

☐ Yes - Product Hold or Withdrawal (see Note 1)

☐ No - Recall possible, proceed with risk analysis

Where is product sold? (Please list all
customers/retailers and include their location)

Approximately how much product has been
sold?

Has product been exported? This includes all
product sold outside of NZ including exports to
Australia & the Pacific Islands

Please tick one below:

☐ Yes ☐ No

If YES which countries?

CONSUMPTION INFORMATION

How is this product commonly used (e.g.
eaten immediately, stored for a few days,
stored for a long period of time in
freezer/pantry)?

How much of this product is usually eaten in
one sitting and how often?
Is it Ready-To-Eat?

CONSUMER/MEDICAL REPORTING (Note 3)

Have there been consumer complaints about
this product?

Please tick one below:

☐ Yes ☐ No

If YES give details

Any reports of illness or injury?

Please tick one below:

☐ Yes ☐ No

If YES give details

EXPERT OPINION (Note 4)

Note experts consulted, and results of
consultation.

ANY OTHER RELEVANT FACTORS

This section should be used to record anything
else that influences the recall decision.

Hazard/Risk Assessment indicates Recall Required? Please tick one below:

☐ Yes

☐ No

☐ Maybe - insufficient information to make accurate scientific assessment. Precautionary principle to be used.

Precautionary Principle: Where assessment of available information indicates the possibility of harmful effects on health but scientific uncertainty exists, assume the product presents a risk to human health and take appropriate control action.

Issued 22 September 2014

Final recall decision (including the extent of the finalised scope of the recall (batches, distribution etc)) and key reasons:

Please attach photo(s) of product including an image of batch identification details and its location on the label when returning this form

NON MANIPULATION CERTIFICATE*

DESCRIPTION OF GOODS & DETAILS OF SHIPMENT.....

1. DETAILS: Country of export....

Date of export: _____ c. Country of export: _____
Bill of lading no.: _____ d. Port of export: _____

2. DETAILS: Transit/Intermediary country....

a. Date of entry: _____ d. Port of entry: _____
b. Bill of lading no.: _____ e. Date of export: _____
c. Country: _____ f. Port of exit: _____

3. Detailed description of goods _____

DECLARATION.....

I, the undersigned, declare that the information above is true and correct and that the described goods did not enter into free circulation and were not released from customs control in above mentioned intermediary country.

A SEPARATE FORM IS REQUIRED FOR EACH TRANSIT COUNTRY.

NAME OF DECLARENT, TITLE/POSITION.....

Name of exporter in transit/intermediary country Printed/typed name & position of
authorized person

Signature of authorized person

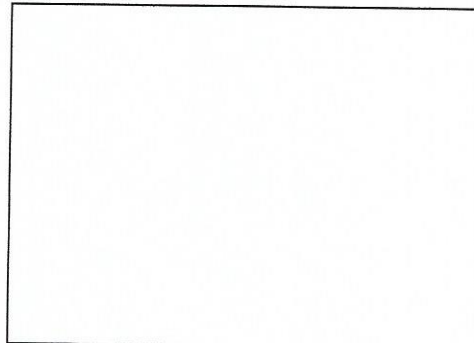
4. CUSTOMS OFFICIAL CONFIRMATION & SEAL

The goods described above have:

Not been released from customs control and
Not undergone any working or processing.

Name of certifying **customs** official
(printed or typed)

Signature of certifying **customs** official



OFFICIAL SEAL/STAMP OF CUSTOMS OFFICE

Customs port/station: _____ Date: _____

* This form may be reproduced and is required in order to determine if the aforementioned goods were released from customs control in the transit/intermediary country.

Procedures for Non-complying Product and Recall

General requirements and Procedures

Ensure non-complying product is appropriately managed

Notify our RMP Officer and MPI immediately when there is a safety concern re any of the products –

beermp@asurequality.com

Murray Reid Asure Quality

Phone 0508001122

Email: Murray.Reid@asurequality.com

MPI

Phone 0800 008383

Email: info@mpi.govt.nz

Complete an international Non- Manipulation Certificate for international exports, arrange shipping back to NZ

Check inventory control to determine if any other product may be affected. Commence a product recall of the affected product if it has been released for sale i.e.

Consumer Level Recall: to remove unsafe food from the distribution chain and extends to food sold to consumers which involves communication with consumers (see mock recall for guidance)

A Consumer level recall should be initiated when food has been identified as unsafe and has been distributed to the consumer and there is a reasonable possibility unsafe food may cause health consequences or death. Examples; the presence of pathogenic organisms e.g. Clostridium botulinum, Salmonella species, Listeria, pathogenic viruses, toxic chemicals or foreign bodies e.g. glass fragments or hard plastic. Incorrect labelling.

Trade Level Recall: this is the removal of unsafe food from the distribution chain but does not extend to food sold to the consumer.

Generally, a trade level recall should be initiated when food is unsafe, a potential risk to the public health but it can be demonstrated that the unsafe

products remain wholly in the distribution chain and have not reached the consumer, there are some situations where food is distributed to the consumer but circumstances indicate a trade level recall will be sufficient to protect public health. This decision needs to be made in consultation with MPI.

Option 1. Permanent removal of the unsafe products from the market and disposal.

Option 2. Temporary removal of the unsafe products from the market, followed by correction of the problem by reworking, repacking, or relabeling and a return to the market.

Handle and store non-complying products separately from complying products:

- . to prevent contamination of other products
- . to prevent contamination of the storage environment

Non-complying products should be:

- . clearly identified
- . separated from other products
- . recorded in inventory as unavailable for load out
- . held within the premises until disposition is determined by a suitably skilled person to determine:
 - . product safety and suitability
 - . amount of product affected
 - . whether the product has been released for distribution or not
 - . whether the products can be reprocessed
 - . any instructions from MPI or RMP verifier

Keep records to demonstrate compliance with the requirements
Keep records for non-complying product:

- . inventory or list of non-complying products
- . records of assessment and disposition of non-complying products
- . records of recall activities including mock recalls
- . inventory records
- . any correspondence with verifier or MPI

Roles and Responsibilities

Recall Coordinator to stop all distribution of the product in question and arrange for return of product to collection point. Prepare inventory and distribution status of product showing where when and to whom and quantity sold.

Prepare batch identification.

Investigate cause of problem

Prepare response to consumers. Answer all consumer enquiries.

Set up stock reconciliation to determine cost of recall.

Handle all legal implications

Handle press releases – manage all media contact

Consult with regulatory agencies

Arrange for pick up from retailer

Arrange for credit to be given

Assist in pick up and arrange for delivery of credit notes

Version 2
13.06.19
- DWO

Claudio Innocenti 24.4.A

Mock Recall Decision

Noticed a fitting missing from packing machine – noticed 13th February 2019.

Recall coordinator notified. CEO notified

Assessed as a potential choking hazard

MPI notified.

Verifier notified

Began recall plan

Suspended distribution of product – notified Mill Street Pak N Save

Collated traceability information

Confirmed Health Hazard

Confirmed product distributed to consumers

Carry out recall

Version 2
dated 28.06.19

(MOCK) PRESS RELEASE – for immediate release

13th February 2019

Bees Inn Apiaries 500gram Clover Honey Batch 221 Best Before 2022 (10 cartons) is being recalled due to concerns that there may be a choking hazard present.

Bees Inn Apiaries are conducting a voluntary recall of their 500gram Clover Honey Batch 221 Best Before 2022 - from Mill Street Pak N Save Hamilton after noticing a fitting from the packing machine was missing after processing.

Consumers are asked to return this product to the place of purchase for a full refund. The retailer has been advised of this recall.

This recall does not affect any other Bees Inn product.

Consumers requiring further information should please contact:

Bees Inn Apiaries
27 West Road
Ohaupo
(PH) 07 8236 513
Email: dave-west@xtra.co.nz

Version 2
Created 23.06.19

Claudio Innocenti

The Manager
Mill Street Pak N Save
Mill Street
Hamilton

13 Feb 2019

RECALL:

SUSPEND DISTRIBUTION OF: 500 GRAM CLOVER HONEY BATCH 221 BEST BEFORE 2022 10 CARTONS

Bees Inn Apiaries are conducting a voluntary recall of the 10 cartons of 500gram Clover Honey Batch 221 due to a concern there may be a choking hazard present from a stainless steel fitting missing off the packing machine.

Please advise how many cartons of this honey have been sold.

Consumers are being advised to return this product to you for a full refund. We will arrange credit notes to be given and collection of unsold products.

This recall does not affect any other Bees Inn product.

Regards

Christine West
Bees Inn
PH 07 8236 513
Email:dave-west@xtra.co.nz

Version 2
Created 28.02.19
DW.

Claudio Innocenti

Mock Recall

FOOD RECALL

BEES INN

MANUKA HONEY

500 gram

Batch 221

Best Before 2022

Bees Inn are initiating a recall of their Manuka Honey after discovering that this product may contain a piece missing from the packing machine. All 500gm Manuka Honey with Batch 221, best before 2022 should not be consumed.

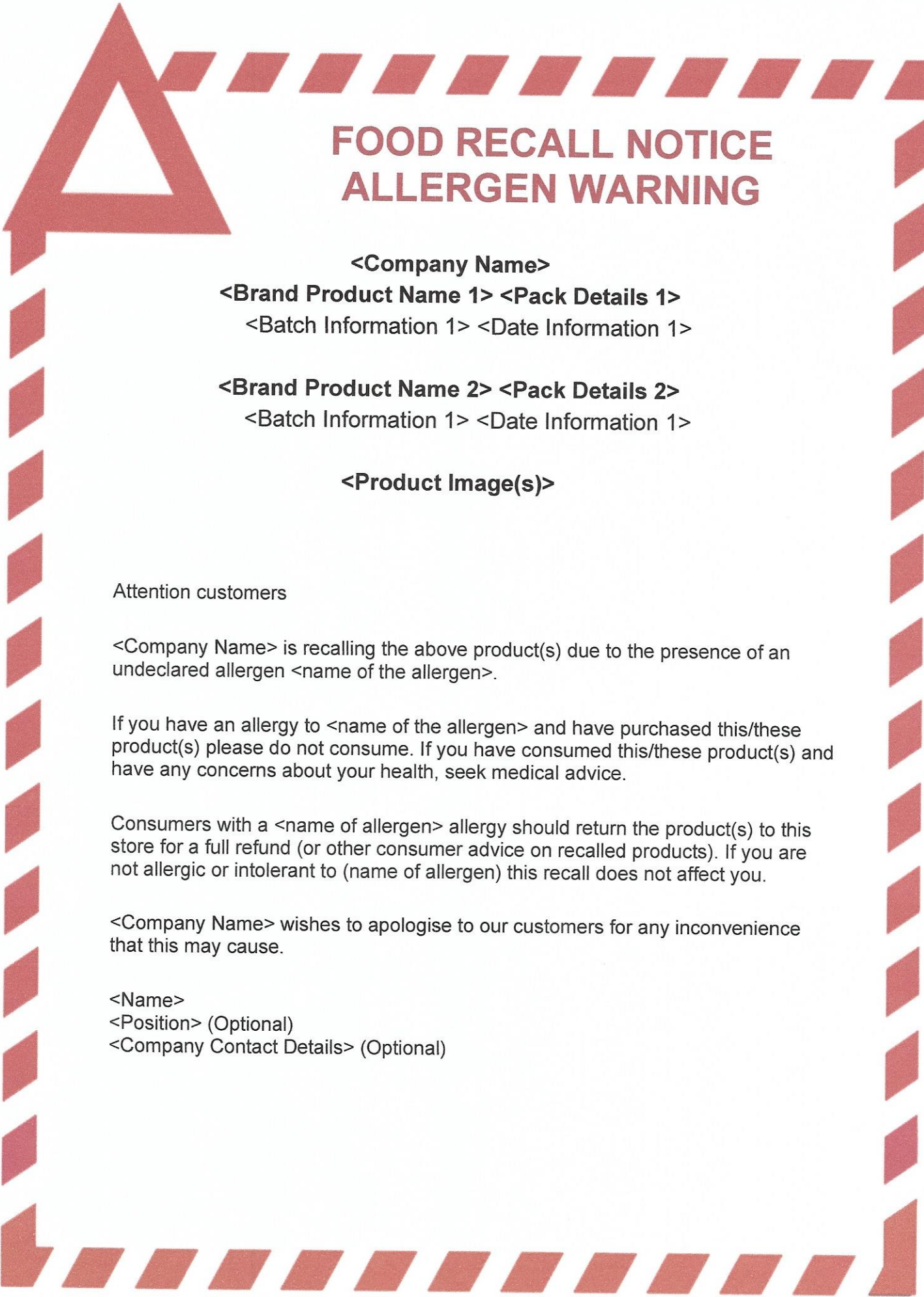
There have been no reports of illness, however any person concerned about their health should seek medical advice.

The product is sold in Pak 'n' Save Mill Street, Hamilton only. Customers should return the product to their retailer for a full refund or phone 07 823 6513 with any queries.

This recall does not affect any other Bees Inn product.

Bees Inn
27 West Road
Ohaupo

Version 2
Created 28.06.19.
AW.



FOOD RECALL NOTICE ALLERGEN WARNING

<Company Name>

<Brand Product Name 1> <Pack Details 1>

<Batch Information 1> <Date Information 1>

<Brand Product Name 2> <Pack Details 2>

<Batch Information 1> <Date Information 1>

<Product Image(s)>

Attention customers

<Company Name> is recalling the above product(s) due to the presence of an undeclared allergen <name of the allergen>.

If you have an allergy to <name of the allergen> and have purchased this/these product(s) please do not consume. If you have consumed this/these product(s) and have any concerns about your health, seek medical advice.

Consumers with a <name of allergen> allergy should return the product(s) to this store for a full refund (or other consumer advice on recalled products). If you are not allergic or intolerant to (name of allergen) this recall does not affect you.

<Company Name> wishes to apologise to our customers for any inconvenience that this may cause.

<Name>

<Position> (Optional)

<Company Contact Details> (Optional)



SUPPLIER QUESTIONNAIRE

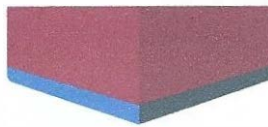
for

U.S. IMPORT ENTRY

UNDER FSVF



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OVERVIEW of REGULATIONS

The Foreign Supplier Verification Program (FSVP) was published by the FDA on November 27, 2015. FSVP is fundamentally concerned with food safety. As a validly designated and qualified United States (U.S.) representative, United Safety Agents LLC's (USA) FDA-mandated goal is to verify that a product's innate physical, chemical and biological hazards are being controlled prior to public consumption, and in a manner that provides at least the same level of public health protection as the FDA's domestic standards (*Preventive Controls Rule, Produce Safety Rule, etc.*). To accomplish this goal, insight into each product's production process and control methods will be required.

INSTRUCTIONS

We respectfully request that every entity/facility that controls any food safety hazard complete this Questionnaire. All sections are required, unless explicitly noted otherwise. **Complete via computer, do not print.**

Upon completion: Please return this questionnaire and accompanying documents via:

Method One: e-mail completed questionnaire to info@unitedsafetyagents.com

Method Two: upload completed questionnaire to USA's [ShareFile](#)

CONFIDENTIALITY

All information shared will remain strictly privileged & confidential and will ONLY be used during FSVP certification activities. An accurate and truthful response is required to successfully complete your company's FSVP certification. This document contains information which is privileged, confidential, and protected. Any disclosure, copying, distribution, or use of the contents of this message is prohibited. Document may contain Non-binding recommendations. United Safety Agents provides FSVP compliance services to businesses and has no direct affiliation with the FDA.

CONTACT

If you have any questions or require additional information, please contact United Safety Agents LLC directly via Email: info@unitedsafetyagents.com; Phone: +1 (888) 551-7403; Fax: +1 (888) 557-2649; UnitedSafetyAgents.com, or by Mail: 715 West Park Avenue, No. 222, Oakhurst, New Jersey 07755, United States of America.



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GENERAL INFORMATION

Company Name: **Bees Inn** Today's Date: **April 14 2021**

Factory Address: **27 West Road**

City: **Ohaupo** Province: **Waikato** Country: **New Zealand**

Office Address: **27 West Road**

City: **Ohaupo** Province: **Waikato** Country: **New Zealand**

FDA Registration No.: **16802114790** DUNS No.: **593151462**

FDA Establishment Id.: **16802114790** Phone No.:

QC/QA's Name: **Christine West** E-mail: **dave-west@xtra.co.nz**

SUPPLIER CLASS

Please select all actions/roles that apply to your facility/operation.

- | | | | |
|--|--|----------------------------------|------------------------------------|
| ☐ Manufacturer (Raw Material) | ☐ Processor | ☐ Packer | ☐ Re-Packer |
| ☐ Manufacturer (Finished Product) | ☐ Distributor | ☐ Shipper | ☐ Warehouse |
| ☐ Importer (US-based) | ☐ Exporter (Non US-based) | ☐ Broker | ☐ Other |

RESPONSIBILITIES for HAZARD CONTROLS

Please select the appropriate response for each hazard type that your facility/operation controls.

- | | | |
|--|---|-----------------------------|
| Is your factory/facility responsible for controlling Biological Hazards? | ☒ Yes | ☐ No |
| Is your factory/facility responsible for controlling Chemical Hazards? | ☒ Yes | ☐ No |
| Is your factory/facility responsible for controlling Physical Hazards? | ☒ Yes | ☐ No |
| Is/Are product(s) in Ready-to-Eat form when exiting your factory/facility? | ☒ Yes | ☐ No |

PRODUCTS SUPPLIED

Please list the name (and variation) of each product that your facility/operation supplies.

No. 01, Product Name: **Honey** Product No.: **ZHPOHYN000**

No. 02, Product Name: Product No.:

No. 03, Product Name: Product No.:

No. 04, Product Name: Product No.:

No. 05, Product Name: Product No.:

No. 06, Product Name: Product No.:

[Resources](#)

[FDA Product Codes and Product Code Builder](#)

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FDA - IDENTIFIED BIOLOGICAL HAZARDS

FDA-identified Biological Hazards associated with the product(s) that your company supplies.

- | | | | |
|---|---|--|--|
| ☐ Bacillus cereus | ☒ Clostridium botulinum | ☐ C. perfringens | ☐ Brucella spp. |
| ☐ Campylobacter spp. | ☐ Pathogenic E. coli | ☐ Salmonella spp. | ☐ S. aureus |
| ☐ L. monocytogenes | ☐ Trichinella spiralis | ☐ Giardia lamblia | ☐ Shigella spp. |

Resources



Appendix 1



Description of Hazard



Bad Bug Book

CRITICAL CONTROLS for BIOLOGICAL HAZARDS

Please select and describe the method by which Biological Hazard(s) are controlled. Please be as detailed as possible. Include time/temperature, chemical names, or any other information.

☐ Heat

☒ Chemical

☒ CGMPs

☐ Testing

☐ Other

DESCRIPTION of CRITICAL CONTROLS

Clostridium botulinum - risk medium. Ensure all equipment is thoroughly cleaned using approved cleaning maintenance compound - microdect 750B 10 - 20ml per litre of water applied at a temperature of 60c for 10-20 minutes then washed off and dried before use.

Do not sit honey supers directly on the ground - place honey supers on clean stainless steel drip trays.

Yeast - Keep extracted honey in airtight containers - vats covered so as not to be exposed to air for extended periods of time Granulated honey should not be exposed to moisture or air to prevent fermentation

UNITED STATES FOOD & DRUG ADMINISTRATION'S PRODUCT HAZARD PROFILE

FREQUENCY of CONTROL VALIDATION

All equipment is to be cleaned after each use and checked before re-using. Cleaning of processing rooms to be recorded in the cleaning schedule

FDA - IDENTIFIED CHEMICAL HAZARDS

FDA-identified Chemical Hazards associated with the product(s) that your company supplies.

- | | | | |
|--|---------------------------------------|--|--|
| ☐ Drug residues | ☐ Heavy metals | ☐ Industrial chemicals | ☒ Pesticides |
| ☐ Mycotoxins/Toxins | ☐ Radiological | ☐ Unapproved colors & additives | ☐ Other |

Resources



Appendix 1



Description of Hazard



Bad Bug Book

CRITICAL CONTROLS for CHEMICAL HAZARDS

Select and describe the method(s) by which Chemical Hazard(s) are controlled. Please be as detailed as possible.

☒ CGMPs

☐ Testing

☐ Other

DESCRIPTION of CRITICAL CONTROLS

Varroa destructor - Manufactures instructions to be followed when using Mite treatments, do not apply when honey supers on the hive. Mite treatments applied March 1st to the end of April = 60 days and again October 1st to end of November = 60 days.

Extracted supers to be stored sticky not dry so as to avoid wax moth infestation

Cleaning agents - Only MPI approved cleaning agents are to be used on beekeeping equipment and in processing areas. Manufactures instructions are to be followed.

Toxic Plants and Pesticides - Tutin and Pesticides tested at an accredited laboratory, we use Analytical Laboratory.

UNITED STATES FOOD & DRUG ADMINISTRATION'S PRODUCT HAZARD PROFILE

FREQUENCY of CONTROL VALIDATION

Varroa treatments applied March and April for 60 days and again in October and November. Oxalic acid used in between these dates if needed. No treatment is to be on the hives while the honey supers are on the hive.

A register of approved and non-approved maintenance chemical compounds is to be kept. Measuring containers are to be labelled for chemical use only. Personal are to be trained in the correct handling and use of chemicals. Directions posted on the wall. Equipment and contact surfaces are to be thoroughly washed off after exposure to any maintenance compound. Empty chemical containers are to be disposed of according to manufactures instructions and not re-used for any purpose within the facility.

If a Tutin test fails blend honey and re-test to obtain a pass result.
Test for pesticides as per importing country requirements.

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FDA - IDENTIFIED ENVIRONMENTAL/PROCESS HAZARDS

FDA-identified Environmental Hazards associated with the product(s) that your company supplies.

- | | |
|---|---|
| ☐ Recontamination with environmental pathogens. | ☐ Bacterial pathogen survival of a lethal treatment. |
| ☐ Bacterial growth and/or toxin formation due to lack of time / temperature control. | ☐ Recontamination due to lack of container integrity. |
| ☐ Bacterial growth and/or toxin formation due to reduced oxygen packaging. | ☐ Bacterial growth and/or toxin formation due to poor formulation control. |

Resources



Appendix 1



Description of Hazard



Bad Bug Book

CRITICAL CONTROLS for ENVIRONMENTAL HAZARDS

Select and describe the method(s) by which Environmental Hazard(s) are controlled. Be as detailed as possible.

- ☐ Heat
- ☐ Chemical
- ☐ CGMPs
- ☐ Testing
- ☐ Other

DESCRIPTION of CRITICAL CONTROLS

Varroa Destructor - mite control applied March 1st to the end of April and October 1st to the end of November each year

UNITED STATES FOOD & DRUG ADMINISTRATION'S PRODUCT HAZARD PROFILE

Note: Please fill the following

Category:
Category No.:
Subcategory:
Storage:

FREQUENCY of CONTROL VALIDATION

Twice yearly for 60 days at a time, after the honey flow and before the next season honey flow.

No mite treatments are to be on the hives in the honey producing season.

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FDA - IDENTIFIED PHYSICAL HAZARDS

FDA-identified Physical Hazards associated with the product(s) that your company supplies.

- | | | | |
|---------------------------------|--------------------------------|--|-----------------------------------|
| ☐ Metal | ☐ Glass | ☐ Extraneous Matter | ☐ Plastics |
| ☐ Stones | ☐ Wood | ☐ Natural Component of Food | ☐ Other |

[Resources](#)



[Appendix 1](#)



[Description of Hazard](#)



[Bad Bug Book](#)

CRITICAL CONTROLS for PHYSICAL HAZARDS

Select and describe the method(s) by which Physical Hazard(s) are controlled. Please be as detailed as possible.

☒ CGMPs

☐ Testing

☒ Raw Material Inspection

☒ Filter

☐ Screen

☐ Metal Detector

☐ Magnet

☐ X-Ray

☐ Radar

☐ Other

DESCRIPTION of CRITICAL CONTROLS

Dust/Dirt - Do not place supers of honey directly on the ground. Place on clean stainless steel drip trays in the apiary, during transport and in the extraction area

Insect debris and wax particles - Use double filtration down to 200 micron

Honey jars - inspect honey jars prior to filling - discard any damaged or contaminated containers.

Wood - Ensure hives are sound and undamaged, do not use damaged hive parts. Use double filtration to remove all particles.

Metal - Regularly inspect all metal tools and equipment for wear, rust or damage. Do not use honey if contamination is found.

FREQUENCY of CONTROL VALIDATION

Ensure enough clean stainless steel trays are loaded on the truck when going out to harvest honey.

All honey is to be filtered

Inspect honey jars before and during every pack of honey - discard damaged or contaminated containers.

Metal - inspect metal tools and equipment for rust, wear or damage. Discard honey if contamination is found

Metal detection standards

Ferrous: _____ mm

Non-Ferrous: _____ mm

Stainless Steel: _____ mm

ALLERGEN & CROSS-CONTAMINATION CONTROLS

Component or Ingredient	Present in product?	Present on same equipment?	Present in same facility?
Peanuts	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Tree Nuts	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Milk or Milk Derivatives	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Egg or Egg Products	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Fish	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Shellfish	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Soy	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Gluten	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Wheat	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Celery	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Sesame	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Mustard	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Sulfates	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Monosodium Glutamate	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Colorings	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
Aflatoxins	☐ Yes ☒ No	☐ Yes ☒ No	☐ Yes ☒ No
ALL ALLERGENS	☒ Absent	☒ Absent	☒ Absent

DESCRIPTION of ALLERGENIC CONTROLS

Honey is to be tested for Tutin by an Accredited Laboratory before sale.

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ONSITE AUDITING INFORMATION

Does the manufacturing/processing site have a recognized GFSI certification (BRC, SQF, Etc.)? ☐ Yes ☒ No

If Yes; Please provide a copy of the **full audit report** (written in English).

What standard is the GFSI certification? _____

If No; 1. Does the site have a documented quality manual? ☐ Yes ☒ No

2. Does the site undergo internal hygiene audits? ☐ Yes ☒ No

3. Does the site undergo quality system audits? ☐ Yes ☒ No

4. Does the site undergo process audits? ☐ Yes ☒ No

CLEANING INFORMATION

Does the site have documented hygiene procedures in place? ☒ Yes ☐ No

Does the site have a designated hygiene team? ☒ Yes ☐ No

Are all cleaning staff formally trained? ☒ Yes ☐ No

Do the cleaning schedules include: Chemicals used? ☒ Yes ☐ No

Concentration levels? ☒ Yes ☐ No

Dilution method? ☒ Yes ☐ No

Please list the chemical type(s) used on all food contact lines and surfaces:

Microdet 750B 10-20 ml per litre of water applied to soiled surfaces for 10-20 minutes at a temperature of 60c then rinsed off and dried with paper towels.

STAFF HYGIENE INFORMATION

Have all staff undergone formal food hygiene training? ☐ Yes ☒ No

In-house hygiene training? ☒ Yes ☐ No

Accredited hygiene training? ☐ Yes ☒ No

Training level certification obtained: _____

Are staff issued protective clothing? ☒ Yes ☐ No

Are operatives required to cover head/facial hair within the processing/manufacturing area? ☒ Yes ☐ No

Are adequate toilet and hand washing facilities provided? ☒ Yes ☐ No

Are hand washing/swabbing validation checks carried out? ☒ Yes ☐ No

What is the total number of staff employed on site? 6

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PEST CONTROL

Is a pest control contractor employed?

☐ Yes ☒ No

If yes, please provide: Name of contractor used: _____

Number of yearly visits: _____

If no, by what means is pest prevention carried out? Fortnightly checks on traps monitored by Chris West and re

HACCP & TACCP & VACCP

Does a fully documented and audited HACCP system exist for the site?

☐ Yes ☒ No

Has a hazard analysis study been completed for each site operation?

☒ Yes ☐ No

Does the business have a trained & certified in-house HACCP team?

☐ Yes ☒ No

If yes, please provide copies of current & relevant HACCP training certificates.

Does the business outsource the HACCP management to a certificated consultant?

☐ Yes ☒ No

If yes, please provide copies of current & relevant HACCP training certificates.

Are records maintained for all CCPs?

☒ Yes ☐ No

Does the HACCP system include the following:

Sieving of ingredients?

☒ Yes ☐ No

Sieving of finished products?

☐ Yes ☐ No

Glass & hard plastic breakage procedure?

☒ Yes ☐ No

Metal detection of final product?

☐ Yes ☒ No

Magnets within the mixing & filling stages?

☐ Yes ☒ No

Do you use blue metal detectable plasters in the manufacturing/processing areas?

☒ Yes ☐ No

Please detail any other prevention systems used on-site: _____

Has a full threat assessment of your supply chain been conducted & tested?

☐ Yes ☒ No

Please provide details: _____

Has a full product vulnerability assessment within the supply chain been conducted & tested?

☐ Yes ☒ No

Please provide details: _____

TRACEABILITY

Does full traceability exist for all products supplied to your customer base?

☒ Yes ☐ No

If yes, please give details of traceability codes on the final packaging: Batch numbers, RMP Number

RAW MATERIAL

Are materials used by your company sourced from approved suppliers? ☒ Yes ☐ No

Are certificates of conformance/analysis received for all raw ingredients? ☒ Yes ☐ No

Are raw materials positively released before use? ☐ Yes ☒ No

Please describe your supplier approval system:

An MPI Eligibility Document is received for incoming honey purchased from other beekeepers stating batch & drum numbers, processing date, storage conditions. Tutin declaration - tested or requires testing, treatment type, China and EU declaration and weight.

FINISHED / PACKED PRODUCT

Are finished / packed products positively released? ☒ Yes ☐ No

Are reference samples from finished / packed products retained? ☒ Yes ☐ No

Are finished products submitted to an 17025:2005 accredited laboratory for validation purposes? ☐ Yes ☒ No

If yes, please give details of the testing routines conducted:

CUSTOMER COMPLAINTS

Does a formal customer complaint procedure exist? ☐ Yes ☒ No

Please describe your customer complaint procedure.

we have not had any customer complaints

RECALL / IMPORT ALERT / FOOD SAFETY ISSUE

Has your company ever experienced a recall or other food safety related issue of any kind? ☐ Yes ☒ No

If yes, please describe fully.

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Claudio Innocenti

CERTIFICATION

I certify that the information I provided on and in connection with this form is true, accurate and complete. I also understand that any false statements or deliberate omissions on this document or any other document I file with United Safety Agents, LLC may be grounds for disqualification from successful Foreign Supplier Verification Program (FSVP) approval or, if discovered after FSVP approval takes place, could result in my company's FSVP approval status being revoked or terminated, and may result in my shipments being rejected from entry into the United States. I confirm that all products that my company trades are in compliance with the Food Safety Modernization Act and all other U.S. & FDA Food Safety legislation.

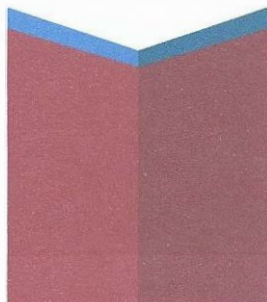


< CONFIRM CERTIFICATION - Required

Representative's Name: Christine West

Title: Owner

Today's Date: 4/14/21



**Bees Inn Manuka Ltd- Samuel &
Christine West
RMP&OAS Verification Audit -
Limited Scope Processor
30-Nov-20**



Assessment Findings

The attached table details the departures from requirements.

The findings are identified as either Non-conformances (NC) or Observations (O).

Non-conformances require actions that are considered necessary to correct omissions/deficiencies and meet the requirements of compliance standards.

An expected timeframe for addressing non-conformances will have been agreed during the audit and is shown in the assessment findings table. When the non-conformances have been addressed to the satisfaction of the assessor you will be issued with a statement of compliance.

Observations do not require responses but may assist in the overall improvement of your systems.

Assessment Findings

	Topic	Assessment Findings Description	Action By
NC 1		Non Conformance <u>Control of Non-Conforming Product, General Export, OAS and QMARs</u> While the drum log captures bulk inventory well, there is no equivalent log for packed honey. Refer E-cert Help Files; Animal Products Notice: Official Assurances Specifications for Animal and Animal Products 2017 clause 7.2 Required Action Set up an inventory control process for packed honey and provide evidence of this to the verifier.	30/12/2020 log for packed honey added to inventory 21.12.20

Observation Findings

	Topic	Observation Findings Description
O 1 ✓		<u>RMP Documents/Operator Verification</u> Document control was effective but the operator was encouraged to capture all documents on a summary page with current version numbers for ease of management.
O 2		<u>Building Maintenance and Cleanliness</u> Building surrounds are in need of a general clean up though a lot of this is due to building activity. It is recommend that a thorough clean up is completed as soon as building activity is completed.

O 3	Personnel Competencies, Training and Hygiene. While records of training were on file, these could be improved by recording the receipt and reading of relevant material from MPI, and signing up to receive MPI updates.
O 4	Traceability, Labelling and Recall. The verifier recommended that the operator reviews the process around receipt and checking of Harvest Declarations to ensure they are completed fully and accurately
O 5	Tutin Requirements. The operator has completed validation testing for the homogenising process in the previous blending tanks. While the new tanks are identical, the verifier recommended validating the homogenisation process in these new tanks.

REPORT ENDS

Assessment Outcome

The following table is a summary of the assessment findings and outcomes.

Period: 1 June - 30 November 2020
Outcome: Acceptable
Current PBV Step: Step 6 (6 Monthly)
Next PBV Step: Step 6 (6 Monthly)

RMP Documents / Operator Verification	Building Maintenance & Cleanliness	Personnel Competency and Training	Traceability, Labelling & Recall	Control of Non-Conforming Product, OAS, and OMARS
1.1 RMP Procedures	2.1 Sign In	3.1 Competencies	4.1 Traceability and Inventory	5.1 Verification of Eligibility Documents(ED"s)
1.2 Physical Boundaries	2.2 Site Reality Check	3.2 Training Records - Management	4.2 Harvest Declarations	5.2 Eligibility Declarations
1.3 Changes to RMP	2.3 Area Separation		4.3 Retail Labelling	5.3 Imported Product
1.4 RMP Coverage	2.4 Lighting		4.4 Bulk / unlabelled retail packs & transportation outers	5.4 Timing of Processing and Dispatch
1.5 Areas and Activities Excluded	2.5 Construction of Equipment		4.5 Recall Procedures	5.5 Export Eligibility Records
1.6 Documentation Requirements	2.6 Containers		4.6 Mock Recall (or equivalent)	5.6 OMAR Knowledge
1.7 Document Control	2.7 Calibration of Equipment		4.7 Transport Documented systems	5.7 EU Listing of Premises
1.8 Record Keeping	2.8 Repairs and Maintenance			5.8 Export Product Storage and Handling
1.9 Operator Verification System	2.9 Repairs & Maintenance Records			5.9 Separation and ID of Non-listed Beekeeper Product
1.10 Annual Review	2.10 Cleaning Indoors			5.10 Separation and ID of Non-EU Product
1.11 Internal Audit	2.11 Cleaning Surrounds			5.11 Translations
1.12 Corrective Action	2.12 Cleaning Records			5.12 Ultra-filtration & Additives
1.13 Operator Verification Records				5.13 Hive Health Status
				5.14 Eligibility Documents - China
				5.15 Manufacturers Declaration

Abbreviations:

Conforming (C)	Observation (O)	Non-conforming (Nc)	Not Applicable (NA)
----------------	-----------------	---------------------	---------------------

Tutin Requirements	Manuka Export Requirements	HACCP and Allergen Control
6.1 Harvest Declarations	7.1 Manuka Testing	8.1 For Extraction of Honey
6.2 Tutin Sampling	7.2 Documentation	8.2 Allergens
6.3 Validation of Blending Process		8.3 Record Keeping
6.4 Tutin Testing		
6.5 Batching of Test Samples		
6.6 Control of Non-complying Honey Products		
6.7 Tutin Compliance Records		

Abbreviations:

Conforming (C)	Observation (O)	Non-compliant (NC)	Not Applicable (NA)
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Company Name: Bees Inn Manuka Ltd- Samuel & Christine West

Address: 27 West Road, RD1, Ohaupo, 3881

Location Visited: Bees Inn Manuka Ltd- Samuel & Christine West
27 West Road
Ohaupo

RMP Identifier: BI3

Type of Assessment: RMP&OAS Verification Audit - Limited Scope Processor

Date of Assessment: 30-Nov-20

Scope of Assessment: Extraction, Transport, Blending/mixing, Melting, Non-refrigerated storage (processes & receives external product)

Reference Standards: Animal Products Act 1999. Animal Products Notice - Official Assurance Specification for Animal Material and Animal Products (29 March 2018). The Risk Management Program and related documents, including Transport Supporting System where appropriate. Operational Code - Processing of Bee Products (15 December 2017) [formerly Code of Practice: Processing of Bee Products]. Relevant Overseas Market Access Requirements (OMARs) including EU and China requirements. Food (Tutin in Honey) Standard 2016. Relevant notices for Transport [Animal Products Notice - Export Requirements for Transportation of Products for Export with an Official Assurance (17 July 2018)]. Animal Products Notice - Export Verification Requirements (07 April 2020). Animal Products Notice - General Export Requirements for Bee Products (GREX) (03 August 2020). Animal Products Notice - Specifications for Products Intended for Human Consumption (14 August 2020).

Assessor / Team: Byron Taylor (BT1)

Report Written by: Byron Taylor

Date: 09-Dec-20

Report Reviewed by: Murray Reid (INS6455)

Date: 10 Dec 2020

Distribution: Chris & Dave West

Date Report Issued to Company: 10-Dec-20

Copy of Report to: Ministry for Primary Industries, Food Assurance | Pastoral House, 25 The Terrace, Wellington
Email: food.assurance@mpi.govt.nz

Contact details

AsureQuality Limited
31 Norman Hayward Drive
Te Rapa
Hamilton
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Byron Taylor
Compliance Auditor
Mobile: 021 918 400
Email: byron.taylor@asurequality.com
Fax: 07 850 2801

Introduction

This assessment was carried out to assess the status of your systems against a nominated standard. The assessment was carried out, in accordance with internationally recognised management system auditing practices such as ISO 17065, ISO 17020 and ISO 19011, against the scope stated in the report.

The auditor will have reported findings verbally in comments to guides or in a closing meeting. This report formalizes those findings, which will be identified as Non-conformances (NC) or Observations (Obs).

Non-conformances are elements where action is required before certification to the nominated standard(s) can be offered or continued, or for recommendation of approvals to be given to external agencies for registration purposes. Where identified, the timeframe for addressing non-conformances is shown in this report.

Actions relating to observations are not mandatory but you are urged to consider them as opportunities for continuous improvement.

Unless otherwise specified, the duration and scope of the audit prevents auditors from covering all aspects of the business especially in relation to legislative requirements such as occupational health and safety. The auditee remains responsible for regulatory and legal compliance of these systems.

Although regarded as a final document the customer should review the report and comment as appropriate. Should there be a conflict relating to the contents, AsureQuality is willing to discuss and amend the report providing the integrity of the findings is not compromised.

Certification/registration may be suspended or withdrawn should noted non-conformances not be appropriately addressed.

Confidentiality Statement

All information obtained during this assessment will remain confidential to your company, AsureQuality and the appropriate regulatory body, if specified in statutory requirements. No information will be released to any other party except with your express permission in writing.

AsureQuality Limited, Level 1, 7a Pacific Rise, Mt Wellington, Auckland.
Ph: 0508 00 11 22 Email: info@asurequality.com www.asurequality.com

Assessment Summary

This scheduled audit was carried out by Byron Taylor (Recognised Person: BT1) of AsureQuality Limited. This report contains the findings of the RMP and OAS verification audit carried out on 30th November 2020 at the premises of Bees Inn Limited.

There were three non-conformances (NCs) raised at the previous audit which have all been closed out. One further NC was raised during this current audit.

Present at the audit: Chris, Dave and Byron.

Company Overview

The operators, Chris and Dave operate this RMP as part of their beekeeping business, which focuses on production of honey and providing pollination services. The previous plant was burnt down in April 2019 and the operators are in the process of rebuilding a new facility on the existing concrete pad. Stage one is complete and operational and consists of an office, an extraction room, a packing room, and a hot room. The latter is currently operating as a storage area. Stage 2 is the larger storage area and is currently framed up and awaiting a roof and wall cladding.

Site Overview

The operator is constructing a copy (albeit, a more modern version) of the previous factory. As such, many of the processes and procedures are similar to those previously used and these are sufficient to ensure that GMP is applied. The RMP boundary on the site plan accurately reflects reality and was version 3 dated 27.11.20. The latest revision added a new lunch room and office to the previous plan. Changes to the RMP have been notified to MPI with a notice on file confirming the moving out of voluntary suspension effective from the 26.11.19. The RMP was placed in voluntary suspension in May 2019. The RMP template is unchanged from pre-fire with just the site plan updated. The new RMP scope covers all activities and processes that occur within the RMP and is similar to the previous scope with the addition of processing and receiving external product. There are activities undertaken within the RMP boundary, which are not covered under the scope of the RMP, but there are adequate controls in place to ensure that they do not impact on RMP activities. This currently includes beekeeping support activity and construction work.

A selection of documents was viewed and all had version numbers and dates. Additionally, an amendment register was on file with the most recent amendment being to the Hygiene procedures to allow for COVID-19 which took place on the 2nd April 2020. While document control was adequate, the operator was encouraged to capture all documents on a summary page with current version numbers for ease of management (**Obs1**).

Records are being built up again as many which existed only as paper records were lost in the fire. The operator intends to keep records for at least 4 years but in practice had previously kept them much longer.

Good operator verification procedures in place with an annual review last completed in January 2020, and 3 monthly internal audits, the most recent being completed on 9th September 2020. The annual review noted the addition of a storage container in May 2019 and that the operation had come out of voluntary suspension in November 2019 (6 months earlier than anticipated). The internal audit noted that the extracting room floor needed repairing before the new season. This was repaired over the 27-29 November 2020. The packing room floor was also repaired in October 2020. Recurring non-compliances are identified & corrective actions undertaken. Corrective actions are completed on internal audit forms both for report findings and also findings outside of internal audits. Machinery issues are captured on a separate corrective action form.

The new building has been constructed on the existing concrete pad. Walls and ceilings in the processing areas are a poly panel construction. The plant is all stainless steel and, while not new, is new to the operator as a single extractor was the only item of plant that survived the fire. The plant all appeared to be adequate for honey processing. The larger storage area (Stage 2 of the rebuild) is still a construction zone and no product is currently stored in the area. There is adequate separation between processing areas and other areas that could contaminate exposed honey. Packing and extracting cells are separated from storage areas. Covered LED lights are used in the processing areas and are of adequate intensity. Scales are calibrated and calibration stickers are attached to all scales. Site repairs and maintenance jobs are done at a time or in a manner that does not risk product contamination. A lot of replacement equipment was installed in December 2019 and the last maintenance check was completed on 13th October 2020.

Cleaning records for the extracting room and packing room are being kept. The building surrounds are in need of a general clean-up as a result of the building activity. It is recommended that a thorough clean-up is completed as soon as building activity is completed (**Obs2**). This is currently scheduled for December 2020.

Both Dave and Chris, the RMP owner/managers, have upskilling declarations which were most recently signed on the 19th November 2019. While competency records for all staff were on file, these could be improved by recording the receipt and reading of relevant material from MPI, and signing up to receive MPI updates (**Obs3**).

Market Access

A tracing exercise was completed for production batch 1021 which was a part of Eligibility Document (ED) NZL2020/BI3/122T. The ED recorded 50 cartons of monofloral manuka honey from batch 1021 sent to Burnard International Ltd for export to Singapore. Test results from Analytica dated 5 March confirmed that the product is Monofloral Manuka honey, and also that the tutin standard had been met (0.47mg/kg). The consignment left BI3 on the 10th November 2020 via TNL1 and a signed consignment note was on file. Drums used in the batch could be traced through a drum log and ultimately back to harvest declarations. While the drum log captures bulk inventory well, there is no equivalent log for packed honey with the operator relying on ED's for reconciliation (**NC1**). The verifier reviewed 12-15 Harvest Declarations for the 2020 season and minor omissions were noted on three of them. The verifier recommended that the operator reviews the process around receipt and checking of Harvest Declarations to ensure they are completed fully and accurately (**Obs4**).

Retail labels for batch 1021 were sighted and appeared compliant. Additionally, a German language label the operator uses was checked and it was confirmed that the requirements of the generic 60B labelling exemption were being followed. Drum labels sighted also met requirements.

The operator does not buy non-EU eligible honey but does have a separation procedure on file if any product was found to be ineligible.

Tutin Requirements, Product Testing and HACCP

All honey is tested for tutin as a blended packing batch however if bulk honey was sold, it would be eligible for human consumption subject to tutin testing. The operator has completed validation testing for the homogenising process in the previous blending tanks. While the new tanks are identical, the verifier recommended validating the homogenisation process in these new tanks (**Obs5**).

The standard HACCP in the Operational Code is adequate with tutin being the only CCP that is monitored.

No bee products with a high risk of allergens, which have to be managed, are processed in this RMP.

A total of **1 non-conformances** were raised as a result of this assessment and will need to be closed out by the action by date. A total of **5 observations** were noted in the interests of continued improvement. These are outlined in the Assessment Findings section on the following pages

Successful closure of the non-conformance (s) will provide verification that the Risk Management Program continues to comply with the requirements under the Animal Products Act 1999 and other associated standards and legislation.

The auditor would like to thank the management and staff for their time and co-operation during the audit.

Product Label - Honey

Product label attached:

We are selling under \$10 million per year,

We will have updated labels in place by July 1st 2021 as per your Changes to the Nutrition Label requirements for Honey.

UMF™ Manuka Honey - Bee's Inn Honey is produced from areas within New Zealand ranging from lush green farmlands to snow-capped mountains where bees collect the honey from Manuka Tree Flowers. The UMF™ grading system appraises natural markers found in Manuka Honey and assures purity and quality. Please see website www.umf.org.nz

Packed by Bee's Inn Manuka Ltd
27 West Road, Ohaupo
New Zealand

RMP B13

Product of
New Zealand
UMF™
Manuka Honey
Packed under Licence
No. 1040

Best Before:
Batch Number:

Bee's Inn



New Zealand Manuka Honey



Net Weight 500g

Servings per package: 25 Serving Size: 20g

	Average Quantity per Serving	Average Quantity per 100g
Energy	268kJ	1340kJ
Protein	0.08g	0.4g
Fat, total	0g	0g
- saturated	0g	0g
Carbohydrates	15.9g	79.6g
- sugars	15.6g	78.1g
Sodium	2.4mg	12mg

Ingredients

100% Pure New Zealand Honey.
No added ingredients.

Warning: Honey is not suitable for children under 12 months. Storage Conditions: Store in a cool place.



9 421905 394093 >

Drum label.

Date: _____

Drum No.: _____

Honey Type: _____

Batch: _____

Yard(s): _____

HD _____ RMP B13
PRODUCT OF NEW ZEALAND

FOA.

Export Pallet Label Template

PRODUCT: *Add Honey variety*

BATCH: #

CARTONS: #

RMP: BI2

NET WEIGHT: kg

PRODUCT OF NEW ZEALAND



Certificate of Analysis

Bees Inn Manuka
NZ Post Centre, Ohaupo
Waikato
Attention: Dave West
Phone: 07 823 6513
Email: dave-west@xtra.co.nz

Lab Reference: 21-16429
Submitted by: Lewis
Date Received: 12/04/2021
Testing Initiated: 13/04/2021
Date Completed: 14/04/2021
Order Number: N/A
Reference: N/A

Report Comments

Samples were collected by yourselves (or your agent) and analysed as received at Analytica Laboratories. Samples were in acceptable condition unless otherwise noted on this report.
Specific testing dates are available on request.

Results Summary

Glyphosate

Laboratory ID	Sample ID	Glyphosate	Glufosinate	Aminomethyl phosphonic acid
	Units Reporting Limit	mg/kg 0.010	mg/kg 0.010	mg/kg 0.010
21-16429-1	20 - 21 #68	<0.010	<0.010	<0.010
21-16429-2	20 - 21 #69	<0.010	<0.010	<0.010
21-16429-3	20 - 21 #70	<0.010	<0.010	<0.010
21-16429-4	20 - 21 #71	<0.010	<0.010	<0.010
21-16429-5	16 - 21 #52	<0.010	<0.010	<0.010
21-16429-6	16 - 21 #53	<0.010	<0.010	<0.010
21-16429-7	16 - 21 #54	<0.010	<0.010	<0.010
21-16429-8	16 - 21 #55	<0.010	<0.010	<0.010
21-16429-9	16 - 21 #56	<0.010	<0.010	<0.010
21-16429-10	12 - 21 #37	<0.010	<0.010	<0.010
21-16429-11	12 - 21 #38	<0.010	<0.010	<0.010
21-16429-12	12 - 21 #39	<0.010	<0.010	<0.010
21-16429-13	12 - 21 #40	<0.010	<0.010	<0.010
21-16429-14	12 - 21 #41	<0.010	<0.010	<0.010
21-16429-15	12 - 21 #42	<0.010	<0.010	<0.010

Glyphosate Approver:

Tracy Chen, B.Sc.
Technologist

All tests reported herein have been performed in accordance with the laboratory's scope of accreditation with the exception of tests marked *, which are not accredited.
This test report shall not be reproduced except in full, without the written permission of Analytica Laboratories.



Analysis Request Form - Honey Testing

Client Information (To Appear on Report)					Comments/Special Instructions											
Company or Client Name																
Contact Person		Phone #														
Address																
E-mail Report To																
Client Reference Max 15 characters		Purchase Order # Max 15 characters			CUSTOM INVOICING DETAILS <i>Only complete if invoice recipient is different from report recipient</i>											
Submitter (if not Client)					Invoice To (Company Name)											
Submitter E-mail/Phone					E-mail Invoice To											
Also Send Results to Submitter <i>(please tick if required)</i>					☐					Test Packs MANUKA PACK – 3-in-1 + free Forecast, MPI 5 Attributes M EXTRACTION PACK – 3-in-1 + free Forecast, MPI 5 Attributes, C4 Screen E PROCESSING PACK – 3-in-1 + free Forecast, MPI 5 Attributes, C4 AOAC P Write the pack code in the 'TEST PACK' column to select all of the tests listed in the pack for a sample at a discounted price.						
Provide Each Sample on Individual Report <i>(please tick if required)</i>					☐											
Include Excel Report <i>(please tick if required)</i>					☐											
Office Use Only																
Laboratory ID Number		Date Received		Received By												
Your Sample Identification (To Appear on Report)		TEST PACK (indicate code)	Manuka Tests				General Honey Tests								Other Tests	
			3-in-1 DHA/MG/HMF/NPA + Forecast	Leptosperin	MPI Manuka Chemical Markers	MPI Manuka DNA Marker	Tutin - Individual	Tutin - Composite Identify groups	C4 Sugars - AOAC	C4 Sugars - Screen	Colour & Conductivity Suite	Moisture Only	Heavy Metals	Diastase		Amitraz
1			☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
2			☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
3			☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
4			☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
5			☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
6			☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
7			☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
8			☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
9			☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
10			☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

Samples will be retained for a maximum of 3 weeks following testing. They can be returned to clients on request for the cost of handling, packaging, and return shipping. On disposal samples may be combined, and resulting bulk honey be made available to Analytica staff for personal use. For test prices, turn-around times, and other information visit www.analytica.co.nz or telephone 07 974 4740.



Foreign Supplier Verification Program

CERTIFICATE of COMPLIANCE

*This certifies that on or about the **SIXTEENTH** day of **APRIL, 2020**, United Safety Agents (USA); as a validly designated and qualified United States (U.S.) representative and FSVP Agent, conducted all requisite foreign supplier verification and related activities for the purpose of compliance with the U.S. Food and Drug Administration's Foreign Supplier Verification Program (FSVP) requirements, and that **NEW ZEALAND REWAREWA HONEY & MANUKA HONEY**, supplied by **BEE'S INN** met the requirements found in section 805 of the Federal Food, Drug and Cosmetic Act, FSVP, and implementing regulations. Certificate **expires** on the **SEVENTEENTH** day of **APRIL, 2021**.*

Please contact USA with any questions.

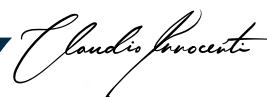

United Safety Agents LLC
Claudio Innocenti
Partner

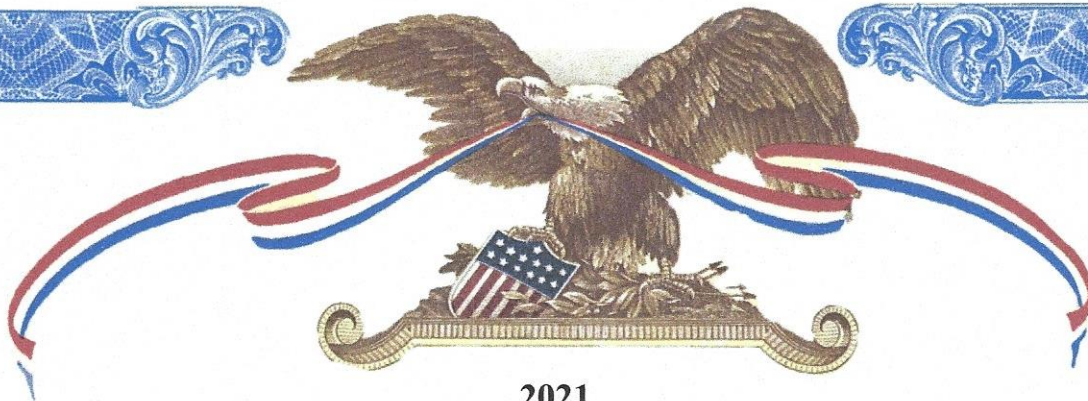
715 W. Park Ave., 222, Oakhurst, NJ 07755 | (888) 551-7403 | UnitedSafetyAgents.com

USA works with private industry and has no direct affiliation with the U.S. FDA.

*Certificate does not guarantee food is safe to consume, only that
actions were taken to fulfil regulatory obligations.*







2021

CERTIFICATE OF REGISTRATION

This certifies that:

**Bees Inn
27 West Road
RD 1
Ohaupo, Waikato 3881
New Zealand**

is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as currently effective on the date hereof by Registrar Corp:

U.S. FDA Registration No.:	16802114790
U.S. Agent for FDA Communications:	Registrar Corp 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

This certificate affirms that the above stated facility is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as effective by Registrar Corp as of the date hereof, and Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until December 31, 2021, unless such registration has been terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp

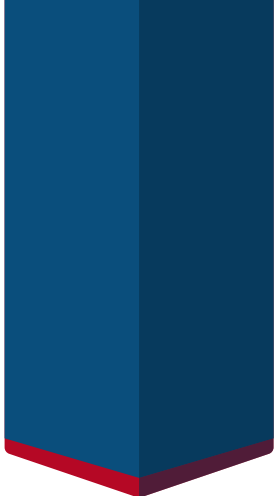
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

A handwritten signature in blue ink, reading "David Lennarz".
David Lennarz
Executive Director
Registrar Corp

Dated: November 4, 2020

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A handwritten signature in blue ink, reading "Claudio Innocenti".



DOCUMENT REQUEST

for

CONTINUED IMPORT
UNDER FSVP

BEES INN

for the benefit of

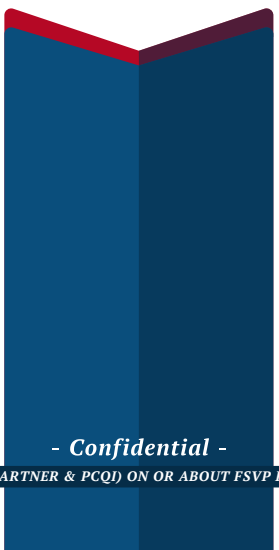
MAR. 30, 2021

as of

- Confidential -

DOCUMENT REVIEWED AND ASSESSED BY CLAUDIO INNOCENTI (PARTNER & PCQI) ON OR ABOUT FSVP PLAN'S NOTED REVIEW START/END DATES

CONFIDENTIAL TREATMENT REQUESTED



FOOD SAFETY DOCUMENTS for FSVP CERTIFICATION

The following documents are respectfully requested as part of the FDA FSVP certification process.



FOOD SAFETY PLAN

Written procedures that fully describe the methods used to safely manufacturer and handle food products.

May include: supplier approval procedure, allergen controls, verification procedures, sanitation controls, etc.

☐ Requested ☐ Required ☐ Received
☒ Updated-Copy Required



HACCP PLAN / HAZARD ANALYSIS

Plan identifies product-specific hazards requiring a control & provides a description of preventive control procedures.

☒ Requested ☐ Required ☐ Received
☐ Updated-Copy Required



ON-SITE AUDIT RESULTS

Annual audit of food safety practices conducted by a qualified auditor. Complete audit report required.

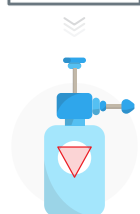
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TESTING RESULTS

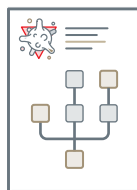
Sampling and testing of product for hazards of concern. *Testing may be done by supplier or 3rd-party lab.*

☐ Requested ☐ Required ☐ Received
☒ Updated-Copy Required



for HAZARDS

☐ Biological (All/Any)
☐ Natural Toxins (Myco/Aflatoxins)
☐ Heavy Metals
☒ Pesticides



RECALL PLAN

Written Recall Plan must include procedures, describe steps, and assign responsibility for actions.

☐ Requested ☒ Required ☐ Received
☐ Updated-Copy Required



PRODUCT LABEL / LABELING

May include: Package label, Bulk label, Nutrition label, Case inserts, Directions for Use, etc. Product label must display any and all present allergens.

☐ Requested ☒ Required ☐ Received
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QUALIFICATIONS

Documentation of personnel's qualifications, training, education, or experience. [PCQI accreditation](#) preferred.

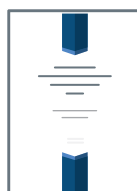
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FDA REGISTRATION

Proof that facility is currently registered with the U.S. FDA – [learn more](#)

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Targeted list of questions designed to help a supplier share the information necessary to comply with FSVP.

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– Please use Questionnaire sent with list.
or [Download a Copy](#)



QUESTIONS?

visit unitedsafetyagents.com/documents
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OVERVIEW of REGULATIONS

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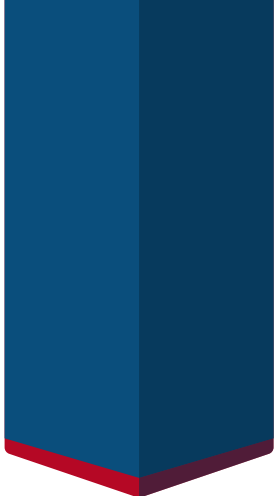


FDA: [Appendix 1](#) – Hazard Profile by Product

[Resources](#)

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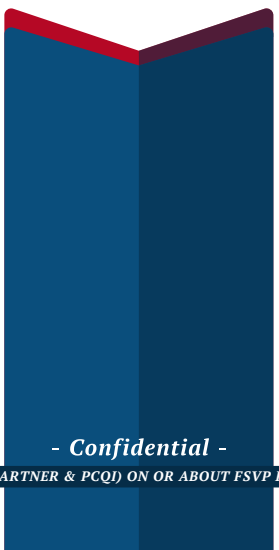
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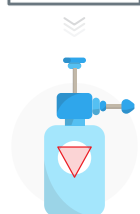
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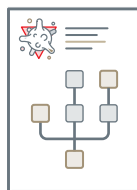
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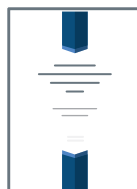
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[Data Dashboard Home\(../index.htm\)](#)

[Compliance Dashboards > \(../cd/index.htm\)](#)

[FSMA Data Search > \(index.htm\)](#)

[How to Use the Dashboard\(../howto.htm\)](#)

[Glossary\(../glossary.htm\)](#)

[Contact Us\(../contact.htm\)](#)

[Home\(../index.htm\)](#) > [FSMA Data\(index.htm\)](#) > [Firm/Supplier Evaluation Resources](#)

Firm/Supplier Evaluation Resources

The FDA firm and supplier database available on this site includes data associated with inspections classification, inspections citations, compliance actions, recalls, and imports.

Search by Firm Name or FEI Number  [Help](#)

3012086164



No data found

Three FDA FSMA rules ([Foreign Supplier Verification Programs \(FSVP\) for Importers of Food for Humans and Animals](#)

(<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals>)

; [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food](#)

(<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food>)

; and [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals](#)

(<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-animal-food>)

) require that importers and facilities perform certain risk-based activities to verify that their suppliers are meeting applicable U.S. food safety standards. Under these rules, you must evaluate, among other things, the applicable FDA food safety regulations and information relevant to the

supplier's compliance with those regulations, including whether the supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation.

Below is a list of publicly available resources that can be used to meet the requirement set out in these regulations as well as information on their use:

Collapse All | Expand All

-  **Warning Letters**
-  **Import Alerts**
-  **Recalls**
-  **Import Refusals**
-  **Inspection Classifications**
-  **Other Compliance Resources**

 **Contact**

Questions and comments pertaining to the FDA Data Dashboard and source data may be directed by email to:
FDADDataDashboard@fda.hhs.gov
(mailto:FDADDataDashboard@fda.hhs.gov)

Dashboard
Home
(../index.htm)

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Inspections
(../cd/inspections.htm)

Compliance
Actions
(../cd/complianceactions.htm)

Recalls
(../cd/recalls.htm)

Imports
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(fser.htm)

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(vqip.htm)

TPP

Help

How to
Use the
Dashboard
(../howto.htm)

Glossary
(../glossary.htm)

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(../contact.htm)

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Import
Refusals

(../cd/imprefusals.htm)

Imports
Entry

(../cd/impentry.htm)

Participants
(tpp.htm)

Language Assistance Available: Español

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(<https://www.fda.gov/about-fda/about-website/language-assistance-services#farsi>) | English
(<https://www.fda.gov/about-fda/about-website/language-assistance-services#english>)



Accessibility

(<https://www.fda.gov/about-website/accessibility>)

Careers

(<https://www.fda.gov/about-website/careers>)

FDA

(<https://www.fda.gov>)

FOIA

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No FEAR

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Nondiscrimination

(<https://www.fda.gov/about-website/nondiscrimination>)

Website

(<https://www.fda.gov>)

Claudio Innocenti

Search Results

FEI Number	Firm Name	Physical Address	Mailing Address
3012086164	Bees Inn	27 West Road, RD 1, Ohaupo, 3881, NZ	C/- NZ Post Centre, 106A Great South Road, Ohaupo, Waikato, 3881, NZ

Procedures for Hazard Analysis HACCP Application

Hazards: Biological

Biological hazards include: pathogenic microorganisms – Clostridium spp, Bacillus spp. Visual inspection and removal of infested combs and good hygienic practises will minimise contamination i.e. cleaning of the pricker and equipment i.e. uncapping knife. Honey supers are to be covered when transporting honey to the processing factory to minimise contamination.

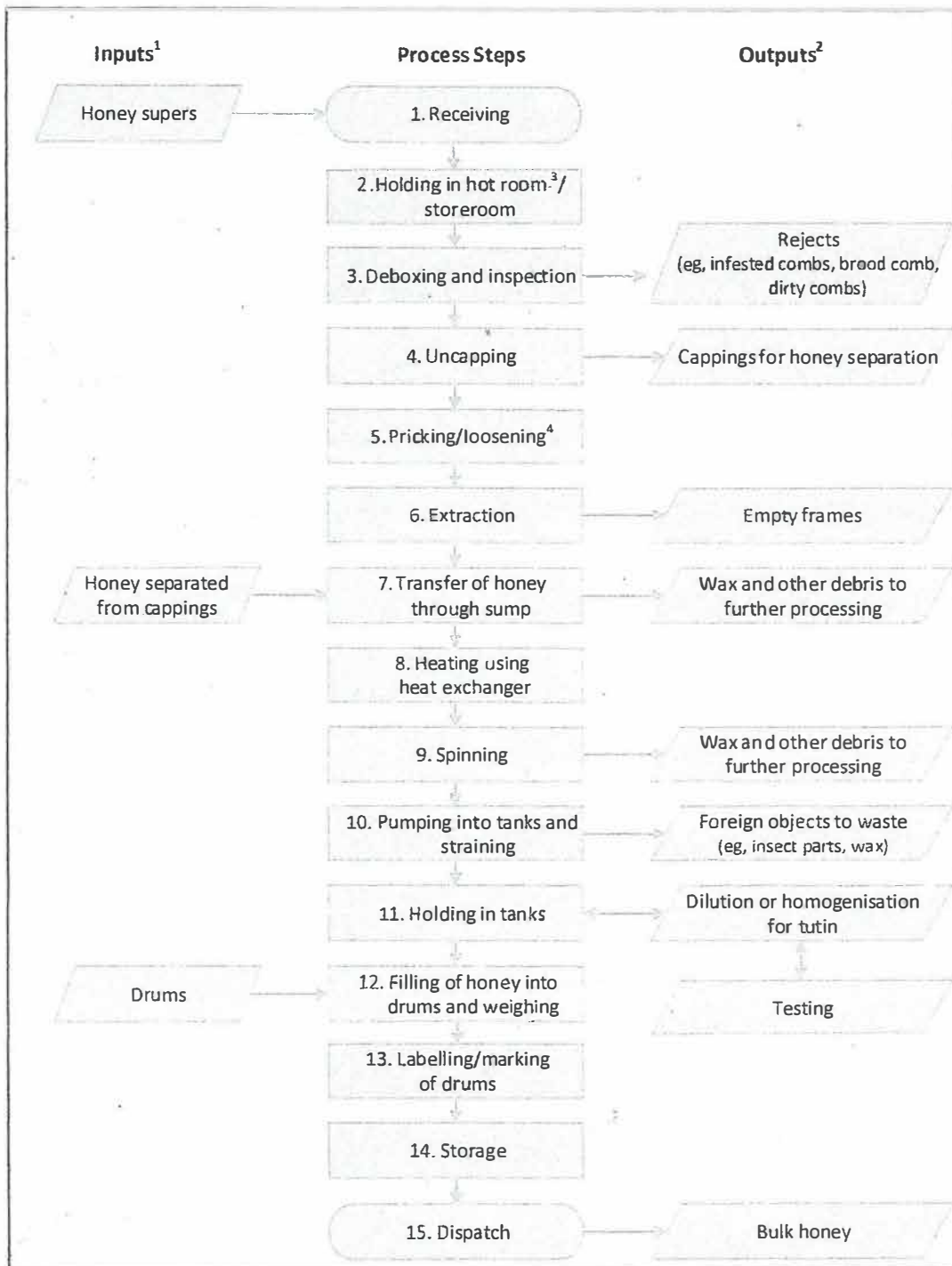
Chemical hazards include: heavy metals, varroacides, pesticides (mite control) veterinary medicines, fungicides, tutin in honey . The control of chemical residues involves monitoring chemical residues and effective beekeeping practises – follow label directions when directly treating hives. If hives are exposed to agricultural chemicals i.e. sprayed pastures the honey should not be extracted, honey to be marked as not for sale and kept separate from saleable honey - contact verifier or MPI for advice.

Each consignment of honey is to have a Harvest Declaration to confirm the controls applied are intended to minimise the risks to human health from agricultural chemicals - pesticides, herbicides and Tutin in honey.

All honey to be tested for Tutin before sale unless it is taken off the hives before 31st December in any given year. The level of Tutin permitted in packed honey is 0.7mg/kg. Comb honey individual samples must be less than 0.01mg/kg. Tutin test results submitted to verifier when raising an ED. See guidance decision tree for Tutin in honey. Drums of honey that do not meet the Tutin requirement level are marked accordingly and held as not for sale until calculations are done to determine how much honey is to be added based on the Tutin level, Tutin test again after blending.

Physical hazards: May cause illness or injury i.e. glass, metal fragments or plastic. Maintenance of frames, cleaning equipment, covering and removal of debris from the sump vat will minimise contamination. Straining and filtering of honey.

Figure 3: Generic process flow diagram for the extraction of honey



1. An input is any material, additive, processing aid, ingredient, or packaging that is added or used for the production or processing of a food product.

2. An output is any material or product resulting from any operation under an RMP.

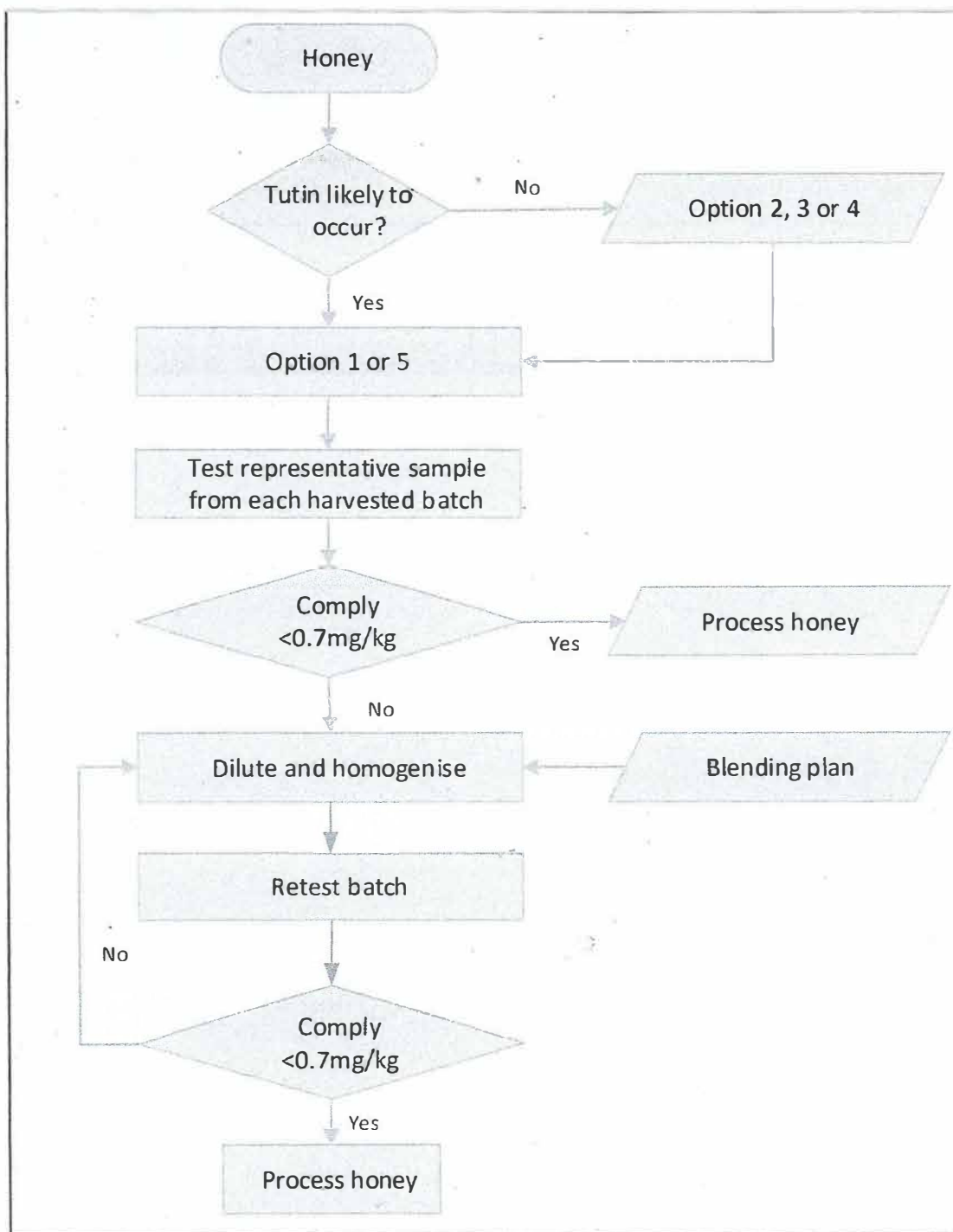
3. Some extractors do not use a hot room, particularly during warm summer days and when only a few boxes of honey are to be extracted (i.e. honey is extracted immediately after harvesting from the hives).

4. Thixotropic honeys, such as manuka, can only be extracted when a pricker/loosener is used to loosen the contents of each honey cell before extraction.

Guidance

The level of 0.7mg/kg of tutin has no safety margin and levels greater than 0.7mg/kg can cause people to experience poisoning symptoms.

Figure 2: Guidance decision tree for tutin in honey



8.2 Identification and control of risks to wholesomeness

Guidance Table 16: Summary of identified risk factors and controls related to wholesomeness of honey

Risk factor	Source or cause of risk factor	Control measures for preventing/ minimising the risk factor
Fermented honey	High moisture content	Measure honey moisture in the comb Proper draining and drying of equipment Preventing water or steam from getting into the product Proper storage
	High yeast level	Hygienic practices Cleaning and sanitation
Insect and insect parts	Bees and other insects	Removal or prevention of ingress of live bees Covering of equipment Pest control Proper storage of supers Straining Freezing or fumigation of comb honey
Other foreign matter that are not considered as physical hazards (e.g. wood, propolis, wax, other debris)	From frames, capping surfaces	Maintenance of frames in good condition Hygienic practices Cleaning and sanitation Proper storage of supers Straining

Guidance Table 17: Summary of identified risk factors and controls related to wholesomeness of dried pollen

Risk factor	Source or cause of risk factor	Control measures for preventing/ minimising the risk factor
Mouldy pollen	High moisture content	Rejection of mouldy pollen at receipt Drying to correct moisture content
	Improper holding temperature	Proper freezing of fresh pollen
	Improper packaging and/or storage	Proper packaging and storage of dried pollen
Foreign matter that are not considered as physical hazards (e.g. wood, wax, insect parts, other debris)	Contaminants from hives, bees and other debris collected in or surrounding pollen traps	Supplier agreements covering good hive maintenance and practices; hygienic collection; incoming material specifications Rejection of fresh pollen with high levels of foreign matter Sieving and cleaning

8.3 Identification and control of risks from false or misleading labelling

Guidance Table 18: Summary of identified risk factors and controls related to false or misleading labelling of honey and other bee products

Risk factor	Source or cause of risk factor	Control measure for preventing/minimising the risk factor
All products		
Incorrect details on label or transportation outers, e.g. • type of product • claims (e.g. organic) • product description • lot identification or batch number • floral species	Incorrect label design	Procedures for ensuring correct label design and compliance with regulatory requirements
	Processing errors, e.g. Wrong identification of drums Wrong product put in a pre-labelled container Wrong label or information put on product (e.g. date, batch number)	Procedures for ensuring correct packaging and labelling of products

PRODUCT DESCRIPTION OF HONEY FOR HUMAN CONSUMPTION

Appearance – Dark brown, Light-dark brown Amber brown. Colour varies season to season and areas produced.

CHEMICAL COMPOSITION OF HONEY

Carbohydrates comprise a large portion of honey – approximately 82% and are fructose (38.2%) glucose (31%) sucrose, maltose, isomaltose

Proteins and Amino Acids. Honey contains a number of enzymes, including invertase which converts sucrose to glucose and fructose. Honey contains eighteen free amino acids.

Vitamins, Minerals and Antioxidants – honey contains trace amounts of B vitamins, riboflavin, folic acid, vitamin B6, vitamin C, minerals calcium, iron, zinc, potassium, phosphorous, magnesium, selenium, chromium and manganese. The main group of antioxidants are the flavonoids. The main acid in honey is gluconic acid formed in the breakdown of glucose.

Packaging - conforms to current EU/FDA regulations for plastic containers and drums

Transport - Honey is transported covered from the hives to the processing factory.

Export honey is transported on RMP registered vehicles only.

Distribution to the customer is ambient, either maritime or air freight.

Storage – Store Honey and packaging materials to:

Minimise contamination, opened cartons of packaging materials are reclosed and covered to prevent dust contamination.

Damaged packaging disposed of.

Storage areas are to be kept clean and tidy.

Honey that is not fit for human consumption or processing, but is suitable for some other purpose must be kept separate and clearly identified and not be a source of contamination to other honey that is intended for human consumption. Discard any raw material when it is contaminated or shows signs of spoilage.

Export suitable honey to be stored separate from non-export honey.

All drums of honey to be stored in a tidy manner, with properly fitting bungs, to prevent moisture and contaminants entering drums.

Store all full and empty drums on a pallet inside the processing factory. Damaged drums are to be disposed of.

Shelf life – 4-5 years.

Intended customer – Warren Pope Tuff Bear

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2. If no, consider hazard at next step.	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit? If yes, this step is a CCP. If no, this step is not a CCP.	CCP no.
	Starter honey	B – Bacterial pathogens	Bacterial spores (e.g. <i>B. cereus</i> , <i>Clostridium</i> spp) may occur in honey	No		
8. Holding in tanks	Liquid or creamed honey	B – Bacterial pathogens	Micro contamination from equipment can occur	Yes – GOP: hygienic practices and cleaning of tanks will minimise contamination	No	
9. Packing and labelling	Honey	B – Bacterial pathogens	Carried over from previous step	No		
	Glass jars & lids	Glass	Pieces of broken glass are occasionally found in glass consignments; jars can also break during handling and processing	Yes – GOP: supplier agreement; visual inspection; correct handling procedures; and proper setting of machines will prevent contamination	No	
	Plastic containers	Plastic pieces	Plastic pieces are occasionally found in container consignments	Yes – GOP: supplier agreement; visual inspection; and correct handling procedures will prevent contamination	No	
10. Storage	Packed honey	B – Bacterial pathogens	Carried over from previous step	No		
11. Dispatch	Packed honey	B – Bacterial pathogens	Carried over from previous step ⁴	No		
		C – Tutin toxin	Carried over from step 1 <0.7mg/kg	No	No	

Version 1
Ministry for Primary Industries
22.2.18
Clean

Claudio Innocenti

Guidance Table 10: Hazard analysis and CCP determination for the processing of liquid and creamed honey

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2. If no, consider hazard at next step.	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit? If yes, this step is a CCP. If no, this step is not a CCP.	CCPno.
1. Receiving	Bulk honey ¹	B – Bacterial pathogens	Bacterial spores (e.g. <i>B. cereus</i> , <i>Clostridium</i> spp) may occur in honey	No		
		C – Tutin toxin	Reported incidence of tutin in NZ honey	Yes – Harvest Declarations confirming beekeeper controls and options 1-5 ²	Yes <i>Lab Reports confirming level of tutin.</i>	1
		C – Chemical residues	Residues may occur in honey ³	Yes – Harvest Declarations confirming beekeeper controls	No	
2. Cleaning of drum external surface	Bulk honey	B – Bacterial pathogens	Carried over from previous step.	No		
3. Heating in hot room	Bulk honey	B – Bacterial pathogens	Carried over from previous step.	No		
4. Transfer of honey into vats/tanks & straining	Bulk honey	B – Bacterial pathogens	Micro contamination from equipment can occur	Yes – GOP: hygienic practices and cleaning of equipment will minimise contamination	No	
5. Heating using heat exchanger	Honey	B – Bacterial pathogens	Carried over from previous step	No		
6. Filtering	Honey	B – Bacterial pathogens	Carried over from previous step	No		
7. Creaming	Honey	B – Bacterial pathogens	Micro contamination from equipment can occur	Yes – GOP: hygienic practices and cleaning of equipment will minimise contamination	No	

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Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2. If no, consider hazard at next step.	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit? If yes, this step is a CCP. If no, this step is not a CCP.	CCP no.
		C – Chemical residues	Residues may occur in honey ³	No	No	

1. It is assumed in this hazard analysis that the bulk honey received has undergone a process which has eliminated any physical hazards (e.g. by straining). Bulk honey that has not undergone effective spinning and/or straining after extraction is likely to contain foreign matter, including objects that may be considered as physical hazards (e.g. wire, stones). The operator who will further process or pack this type of bulk honey must ensure that the relevant physical hazards are identified in their hazard analysis and controlled by their process (e.g. by filtering) [RMP Spec 11 (1)].

2. The Food Standard: Tutin in Honey 2016 describes 5 options for managing tutin in honey to ensure tutin level <0.7mg/kg.

3. Chemical residues can occur when beekeepers or farmers use agricultural chemicals and veterinary medicines in and around hives. Beekeepers must follow all product label directions when directly treating hives and work to minimise bee's exposure to pastures sprayed with agricultural chemicals while honey supers are on their hives. If beekeepers inform you of any potential concerns regarding chemical exposure of bees or honey supers, or declare a known or suspected exposure, defer extracting the affected supers and contact your verification agency or MPI for advice.

4. Vegetative forms of bacterial pathogens (e.g. *Listeria monocytogenes*) have not been detected in honey. However, bacterial spores (e.g. *Bacillus* spp, *Clostridium* spp) may occur in honey. Although these spores will not grow in honey, when it is used as an ingredient in another food, the bacterial spores from honey could be introduced to and grow in that food.

Version 1
Created 20.2.18
Out

7.2.2 Product description

Guidance Table 7: Intended use and consumer of products and product requirements

Product	Liquid or creamed honey	Comb honey	Bulk honey	Wax
Intended consumer	Humans (general public)	Humans (general public)	Humans (general public)	Humans (general public)
Intended use of product that leaves RMP ^{1, 2}	Ready-to-eat Ingredient for preparation of other foods	Ready-to-eat	Further processing and packing to liquid/creamed honey or other honey products Ingredient for preparation of other foods	Further processing into products for pharmaceutical use and manufacture of cosmetics, etc. Further processing into comb foundation Applying as a coating on plastic frames
Regulatory limits ³	Food Standards Code 1.4.1 Sch 19-6 – Tutin 0.7mg/kg	Food Standard: Tutin in Honey 2016 Tutin 0.01mg/kg	Food Standards Code 1.4.1 Sch 19-6 – Tutin 0.7mg/kg	None
Other regulatory requirements specific to honey	Food Standards Code 2.8.2 - Reducing sugars ≥ 60% Moisture ≤ 21%	Food Standards Code 2.8.2 - Reducing sugars ≥ 60% Moisture ≤ 21%	Food Standards Code 2.8.2 - Reducing sugars ≥ 60% Moisture ≤ 21%	N/A
	Animal Products Notice: Contaminant Specifications 2016 Specified chemical substances in honey ≤ maximum permissible levels ⁴	Animal Products Notice: Contaminant Specifications 2016 Specified chemical substances in honey ≤ maximum permissible levels ⁴	Animal Products Notice: Contaminant Specifications 2016 Specified chemical substances in honey ≤ maximum permissible levels ⁴	N/A
Labelling	Labelling of retail packs as specified in the Food Standards Code. Labelling of transportation outers Part 6.6 of this Code.	Labelling of retail packs as specified in the Food Standards Code. Labelling of transportation outers Part 6.6 of this Code.	Labelling of transportation outers Part 6.6 of this Code.	Labelling of transportation outers Part 6.6 of this Code.

1. It is common practice in the New Zealand honey industry to downgrade honey that does not meet certain commercial requirements (e.g. burnt, fermented honey) for animal consumption (e.g. fed to bees or used for stock feed).

2. Wax may also be further processed into products that are not for human or animal consumption (e.g. candles, floor wax, furniture wax).

3. Regulatory limits are limits that are essential to be met for food safety and are established by MPI under the APA and Food Standards Code.

4. Every consignment of honey must be provided with a Harvest Declaration as required by clause 5(1) of Animal Products (Harvest Statement and Tulin Requirements for Export Bee Products) Notice 2010. This statement confirms the controls applied by the beekeeper that are intended to minimise the risks to human health from agricultural chemicals (e.g. pesticides, herbicides) and plant toxins, including tulin.

Note: Where the operator is exporting, additional labelling requirements may be described within the export requirements (OMARs).

7.2.4.2 Process step hazard analysis and CCP determination

Guidance Table 9: Hazard analysis and CCP determination for the extraction of honey

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2. If no, consider hazard at next step.	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit? If yes, this step is a CCP. If no, this step is not a CCP.	CCP no.
1. Receiving	Supers	B – Bacterial pathogens	Bacterial spores (e.g. <i>Bacillus</i> spp, <i>Clostridium</i> spp) may occur	No	No	
		C – Tutin toxin	Reported incidence of tutin in NZ honey	Yes – Harvest Declarations confirming beekeeper controls and options 1-5 ¹	Yes	1
		C – Chemical residues	Residues may occur in honey e.g. natural, weed killers, etc. ²	Yes – Harvest Declarations confirming beekeeper controls	No	
2. Holding in hot room/storeroom	Supers	B – Bacterial pathogens	Hazard carried over from previous step	No		
3. Deboxing	Supers	B – Bacterial pathogens	Micro contamination from boxes (e.g. dirt, insect larvae, rodent excretions) can occur	Yes – GOP: visual inspection of combs; removal of defective and infested combs; and hygienic practices will minimise contamination	No	
4. Uncapping	Combs	B – Bacterial pathogens	Micro contamination from the cappings (e.g. dirt, dust, dead bees, brood, pollen and other foreign matter) is likely to occur	Yes – GOP: hygienic practices; and maintenance of uncapping knife will minimise contamination	No	

Version 1
Created 20.2.18
C.W.

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Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2. If no, consider hazard at next step.	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit? If yes, this step is a CCP. If no, this step is not a CCP.	CCP no.
5. Pricking /loosening	Combs - uncapped - capped	B – Bacterial pathogens	Micro contamination from the pricker/loosener can occur	Yes – GOP: cleaning of pricker/loosener will minimise contamination	No	
6. Extraction	Uncapped or pricked combs	B – Bacterial pathogens	Micro contamination from the comb and frames is likely to occur	Yes – GOP: removal of damaged and dirty combs/frames; and cleaning and maintenance of equipment will minimise contamination	No	
		P – Foreign objects, e.g. wood, wire, nails, plastic	Wood pieces, wire fragments and nails from wooden frames, and plastic from plastic frames can occur	Yes – GOP: maintenance of frames will minimise the hazards Straining of honey	No	
7. Sump	Extracted honey	B – Bacterial pathogens	Micro contamination from the sump and surroundings can occur	Yes – GOP: cleaning of sump; regular removal of debris; and covering of sump will minimise contamination	No	
		P – Foreign objects, e.g. wood, wire, nails, plastic	Carried over from previous step	Yes – GOP: removal of debris from the sump will remove some physical hazards	No	
	Honey separated from cappings	B – Bacterial pathogens	Honey separated from cappings can have higher micro levels.	Yes – Excluding honey from cappings will minimise micro contamination of honey	No	
8. Heating	Extracted honey	B – Bacterial pathogens	Carried over from previous step	No		

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Created 30.1.18

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Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2. If no, consider hazard at next step.	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit? If yes, this step is a CCP. If no, this step is not a CCP.	CCP no.
		P – Foreign objects, e.g. wood, wire, nails, plastic	Carried over from previous step	No		
9. Spinning	Extracted honey	B – Bacterial pathogens	Carried over from previous step	No		
		P – Foreign objects, e.g. wood, wire, nails, plastic	Carried over from previous step	Yes – GOP: most physical hazards are removed when honey is passed through the spinner	No	
10. Pumping into tanks & straining/filtering	Extracted honey	B – Bacterial pathogens	Carried over from previous step	No		
		P – Foreign objects, e.g. wood, wire, nails, plastic	Carried over from previous step	Yes – GOP: any remaining physical hazards are removed by the strainer/filter ³	No	
11. Holding in tanks	Extracted honey	B – Bacterial pathogens	Carried over from previous step	No		
12. Filling into drums & weighing	Extracted honey	B – Bacterial pathogens	Carried over from previous step	No		
	Drums	B – Bacterial pathogens	Micro contamination from left over honey or other food residue can occur.	Yes – GOP: compliance with drum requirements; and cleaning of drums will minimise contamination	No	
		C – Chemical residues	Chemical residues from reused drums can occur.	Yes – GOP: compliance with drum requirements	No	

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Ministry for Primary Industries

Process step	Inputs	Hazard reasonably likely to occur on or in the product at this step	Justification	Q1. Is there a control measure(s) for the hazard at this step? If yes, identify the control measure and then answer Q2. If no, consider hazard at next step.	Q2. Is the control measure at this step essential to food safety as defined by a regulatory limit? If yes, this step is a CCP. If no, this step is not a CCP.	CCP no.
13. Labelling/ marking of drums	Bulk honey	B – Bacterial pathogens	Carried over from previous step	No		
14. Storage	Bulk honey	B – Bacterial pathogens	Carried over from previous step	No		
15. Dispatch	Bulk honey	B – Bacterial pathogens	Carried over from previous step ⁴	No		
		C – Tutin toxin	Carried over from step 1 <0.7mg/kg	No	No	
		C – Chemical residues	Residues may occur in honey ²	No	No	

1. The Food Standard: Tutin in Honey 2016 describes 5 options for managing tutin in honey to ensure tutin level <0.7mg/kg.

2. Chemical residues can occur when beekeepers or farmers use agricultural chemicals and veterinary medicines in and around hives. Beekeepers must follow all product label directions when directly treating hives and work to minimise bee's exposure to pastures sprayed with agricultural chemicals while honey supers are on their hives. If beekeepers inform you of any potential concerns regarding chemical exposure of bees or honey supers, or declare a known or suspected exposure, defer extracting the affected supers and contact your verification agency or MPI for advice.

3. If the operation has no steps for removing foreign matter (e.g. spinner or other strainer device), bulk honey produced from this operation is likely to contain foreign matter, including objects that may be considered as physical hazards (e.g. wire, stones). The operator who will further process or pack the bulk honey must ensure that these hazards are eliminated by their process [RMP Spec 11 (1)].

4. Vegetative forms of bacterial pathogens (e.g. *Salmonella* spp., *Listeria monocytogenes*) have not been detected in honey. However, bacterial spores (e.g. *Bacillus* spp, *Clostridium* spp) may occur in honey. Although these spores will not grow in honey, when it is used as an ingredient in another food, the bacterial spores from honey could be introduced to and grow in that food.

Version 1
Created 20-2-18



Producers & Packers of Honey:
Manuka, Rewarewa, Multi-Flora

Postal Address: NZ Post Centre
106A Great South Road
Ohaupo 3881, New Zealand
Phone: 07 823 6513
Email: dave-west@xtra.co.nz
Physical Address: 27 West Road, Ohaupo



COMMERCIAL INVOICE 7021
ED: NZL2019/BI3/240119

24-01-19

Tuff Bear
1013 N 3rd Ave
Wausau, WI.54401
United States

ITEM	TYPE	DESCRIPTION	UNIT PRICE	QTY DRUM/JARS	WEIGHT	PRICE
1 Pallet	Creamed	5+ Manuka Honey	\$14.50	240 jars	120kg	\$3,480.00
	Creamed	10+ Manuka Honey	\$26.00	408 jars	204kg	\$10,608.00
	Creamed	15+ Manuka Honey	\$23.00	408 jars	102kg	\$9,384.00
	Creamed	20+ Manuka Honey	\$46.00	408 jars	102kg	\$18,768.00
				1464 jars	528kg	
				TOTAL	NZD	* \$42,240.00

* Plus shipping and document costs

Payment is to be made to Bees Inn on arrival of Honey at your factory.

Payment is to be made to: Bees Inn
Account number: 03-0318-0285771-00
Bank: Westpac
426 Victoria Street
Hamilton
New Zealand
Swift Code: WPACNZ2W



Producers & Packers of Honey:
Manuka, Rewarewa, Multi-Flora

Postal Address: NZ Post Centre
106A Great South Road
Ohaupo 3881, New Zealand
Phone: 07 823 6513
Email: dave-west@xtra.co.nz
Physical Address: 27 West Road, Ohaupo



PACKING LIST

ED: NZL2019/BI3/240119

24-01-19

1 Pallet Creamed Honey 122 cartons = 1464 jars

Cartons	Jars per carton	Grams per Jar	Product Description	Packing date
20	12	500	5+ Manuka Honey	17.12.18
34	12	500	10+ Manuka Honey	20.01.19

34	12	250	15+ Manuka Honey	25.10.18
34	12	250	20+ Manuka Honey	10.10.18



Producers & Packers of Honey:
Manuka, Rewarewa, Multi-Flora

Postal Address: NZ Post Centre
106A Great South Road
Ohaupo 3881, New Zealand

Phone: 07 823 6513

Email: dave-west@xtra.co.nz

Physical Address: 27 West Road, Ohaupo



To Minimize Misleading labelling Honey

All batches of honey are on a MPI Spread sheet – Honey Sale Day Sheet for packing.

Please find copy attached.

Dave West
Bees Inn

MPI SPREEDSHEET

Honey Day Sales Sheet For Packing

Buyer Name	BIA Batch	C4	Date	Lab Number	Tu tin	U M F	H M F	MPI Marker DNA	4 HPLA	MBA	MAP	P L A	Mois ture	Season	Drum Number	Drum Batch	HD	Processing Drum Date	Location	Comm

Check List:

	Harvest Docs (HD)
	Tutin test results
	MPI Markers
	MPI DNA
	3 in 1

7.2.2 Product description

Guidance Table 7: Intended use and consumer of products and product requirements

Product	Liquid or creamed honey	Comb honey	Bulk honey	Wax
Intended consumer	Humans (general public)	Humans (general public)	Humans (general public)	Humans (general public)
Intended use of product that leaves RMP ^{1, 2}	Ready-to-eat Ingredient for preparation of other foods	Ready-to-eat	Further processing and packing to liquid/creamed honey or other honey products Ingredient for preparation of other foods	Further processing into products for pharmaceutical use and manufacture of cosmetics, etc. Further processing into comb foundation Applying as a coating on plastic frames
Regulatory limits ³	Food Standards Code 1.4.1 Sch 19-6 – Tutin 0.7mg/kg	<u>Food Standard: Tutin in Honey 2016</u> Tutin 0.01mg/kg	Food Standards Code 1.4.1 Sch 19-6 – Tutin 0.7mg/kg	None
Other regulatory requirements specific to honey	Food Standards Code 2.8.2 - Reducing sugars $\geq 60\%$ Moisture $\leq 21\%$	Food Standards Code 2.8.2 - Reducing sugars $\geq 60\%$ Moisture $\leq 21\%$	Food Standards Code 2.8.2 - Reducing sugars $\geq 60\%$ Moisture $\leq 21\%$	N/A
	Animal Products Notice: Contaminant Specifications 2016 Specified chemical substances in honey $\leq$ maximum permissible levels ⁴	Animal Products Notice: Contaminant Specifications 2016 Specified chemical substances in honey $\leq$ maximum permissible levels ⁴	Animal Products Notice: Contaminant Specifications 2016 Specified chemical substances in honey $\leq$ maximum permissible levels ⁴	N/A
Labelling	Labelling of retail packs as specified in the Food Standards Code. Labelling of transportation outers Part 6.6 of this Code.	Labelling of retail packs as specified in the Food Standards Code. Labelling of transportation outers Part 6.6 of this Code.	Labelling of transportation outers Part 6.6 of this Code.	Labelling of transportation outers Part 6.6 of this Code.

1. It is common practice in the New Zealand honey industry to downgrade honey that does not meet certain commercial requirements (e.g. burnt, fermented honey) for animal consumption (e.g. fed to bees or used for stock feed).

2. Wax may also be further processed into products that are not for human or animal consumption (e.g. candles, floor wax, furniture wax).

3. Regulatory limits are limits that are essential to be met for food safety and are established by MPI under the APA and Food Standards Code.

8.2 Identification and control of risks to wholesomeness

Guidance Table 16: Summary of identified risk factors and controls related to wholesomeness of honey

Risk factor	Source or cause of risk factor	Control measures for preventing/minimising the risk factor
Fermented honey	High moisture content	Measure honey moisture in the comb Proper draining and drying of equipment Preventing water or steam from getting into the product Proper storage
	High yeast level	Hygienic practices Cleaning and sanitation
Insect and insect parts	Bees and other insects	Removal or prevention of ingress of live bees Covering of equipment Pest control Proper storage of supers Straining Freezing or fumigation of comb honey
Other foreign matter that are not considered as physical hazards (e.g. wood, propolis, wax, other debris)	From frames, capping surfaces	Maintenance of frames in good condition Hygienic practices Cleaning and sanitation Proper storage of supers Straining

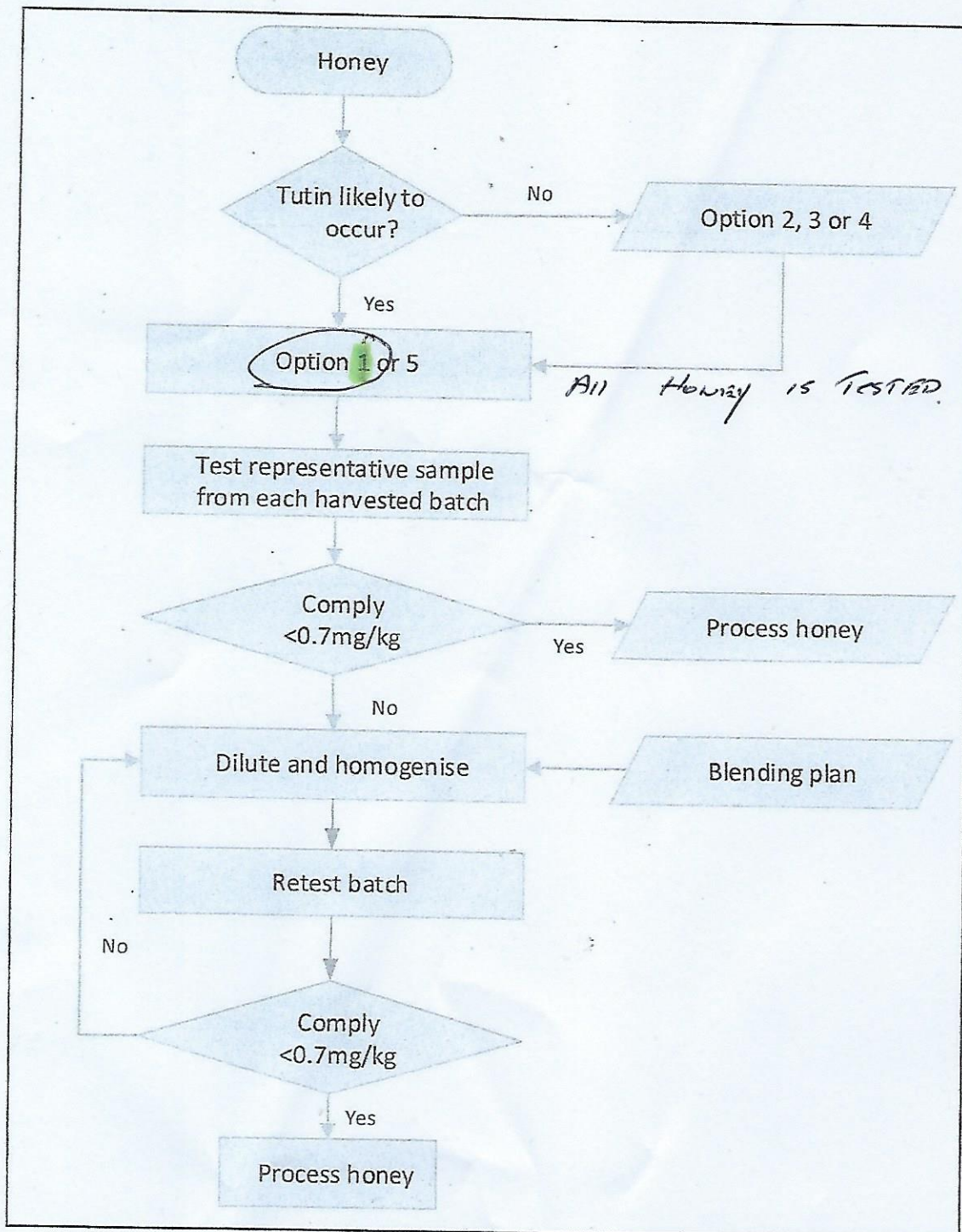
Guidance Table 17: Summary of identified risk factors and controls related to wholesomeness of dried pollen

Risk factor	Source or cause of risk factor	Control measures for preventing/minimising the risk factor
Mouldy pollen	High moisture content	Rejection of mouldy pollen at receipt Drying to correct moisture content
	Improper holding temperature	Proper freezing of fresh pollen
	Improper packaging and/or storage	Proper packaging and storage of dried pollen
Foreign matter that are not considered as physical hazards (e.g. wood, wax, insect parts, other debris)	Contaminants from hives, bees and other debris collected in or surrounding pollen traps	Supplier agreements covering good hive maintenance and practices; hygienic collection; incoming material specifications Rejection of fresh pollen with high levels of foreign matter Sieving and cleaning

Guidance

The level of 0.7mg/kg of tutin has no safety margin and levels greater than 0.7mg/kg can cause people to experience poisoning symptoms.

Figure 2: Guidance decision tree for tutin in honey



Rewarewa Honey - Bee's Inn Honey is produced from areas within New Zealand ranging from lush green farmlands to snow-capped mountains.

Rewarewa is an evergreen tree growing in the low elevations of New Zealand's North Island and the Marlborough Sounds. This tree can grow to 30 metres high. It has very distinctive red flowers.

Rewarewa honey is full bodied with a malt like taste.

Packed by Bee's Inn Manuka Ltd
27 West Road, Ohaupo
New Zealand

RMP B13

Product of
New Zealand
Rewarewa

Best Before:
Batch Number:

Bee's Inn



New Zealand Honey
Rewarewa

Net Weight 500g

NUTRITION INFORMATION

Servings per package: 25 Serving Size: 20g

	Average Quantity per Serving	Average Quantity per 100g
Energy	272kJ	1360kJ
Protein	0.08g	0.4g
Fat, total	0g	0g
- saturated	0g	0g
Carbohydrates	15.9g	79.6g
- sugars	15.6g	78.1g
Sodium	2.4mg	12mg

Ingredients

100% Pure New Zealand Honey.
No added ingredients.

Warning: Honey is not suitable for children under 12 months. Storage Conditions: Store in a cool place.



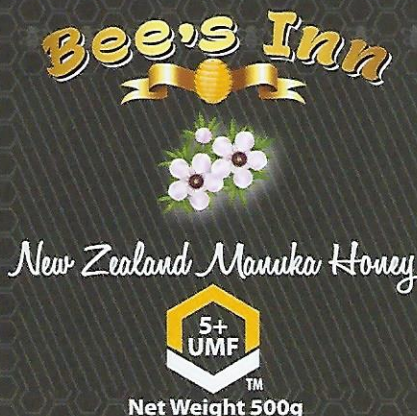
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UMF™ Manuka Honey - Bee's Inn Honey is produced from areas within New Zealand ranging from lush green farmlands to snow-capped mountains where bees collect the honey from Manuka Tree Flowers.
The UMF™ grading system appraises natural markers found in Manuka Honey and assures purity and quality. Please see website www.umf.org.nz

Packed by Bee's Inn Manuka Ltd
27 West Road, Ohapu
New Zealand
RMP B13

Product of
New Zealand
UMF™
Manuka Honey
Packed under Licence
No. 1040

Best Before:
Batch Number:



NUTRITION INFORMATION		
Servings per package: 25		Serving Size: 20g
	Average Quantity per Serving	Average Quantity per 100g
Energy	268kJ	1340kJ
Protein	0.08g	0.4g
Fat, total	0g	0g
- saturated	0g	0g
Carbohydrates	15.9g	79.6g
- sugars	15.6g	78.1g
Sodium	2.4mg	12mg
Ingredients		
100% Pure New Zealand Honey.		
No added ingredients.		
Warning: Honey is not suitable for children under 12 months. Storage Conditions: Store in a cool place.		



UMF™ Manuka Honey - Bee's Inn Honey is produced from areas within New Zealand ranging from lush green farmlands to snow-capped mountains where bees collect the honey from Manuka Tree Flowers.
The UMF™ grading system appraises natural markers found in Manuka Honey and assures purity and quality. Please see website www.umf.org.nz

Packed by Bee's Inn Manuka Ltd
27 West Road, Ohapu
New Zealand
RMP B13

Product of
New Zealand
UMF™
Manuka Honey
Packed under Licence
No. 1040

Best Before:
Batch Number:



NUTRITION INFORMATION		
Servings per package: 25		Serving Size: 20g
	Average Quantity per Serving	Average Quantity per 100g
Energy	268kJ	1340kJ
Protein	0.08g	0.4g
Fat, total	0g	0g
- saturated	0g	0g
Carbohydrates	15.9g	79.6g
- sugars	15.6g	78.1g
Sodium	2.4mg	12mg
Ingredients		
100% Pure New Zealand Honey.		
No added ingredients.		
Warning: Honey is not suitable for children under 12 months. Storage Conditions: Store in a cool place.		



UMF™ Manuka Honey - Bee's Inn Honey is produced from areas within New Zealand ranging from lush green farmlands to snow-capped mountains where bees collect the honey from Manuka Tree Flowers.
The UMF™ grading system appraises natural markers found in Manuka Honey and assures purity and quality. Please see website www.umf.org.nz

Packed by Bee's Inn Manuka Ltd
27 West Road, Ohapu
New Zealand
RMP B13

Product of
New Zealand
UMF™
Manuka Honey
Packed under Licence
No. 1040

Best Before:
Batch Number:



NUTRITION INFORMATION		
Servings per package: 12.5		Serving Size: 20g
	Average Quantity per Serving	Average Quantity per 100g
Energy	268kJ	1340kJ
Protein	0.08g	0.4g
Fat, total	0g	0g
- saturated	0g	0g
Carbohydrates	15.9g	79.6g
- sugars	15.6g	78.1g
Sodium	2.4mg	12mg
Ingredients		
100% Pure New Zealand Honey.		
No added ingredients.		
Warning: Honey is not suitable for children under 12 months. Storage Conditions: Store in a cool place.		



UMF™ Manuka Honey - Bee's Inn Honey is produced from areas within New Zealand ranging from lush green farmlands to snow-capped mountains where bees collect the honey from Manuka Tree Flowers.
The UMF™ grading system appraises natural markers found in Manuka Honey and assures purity and quality. Please see website www.umf.org.nz

Packed by Bee's Inn Manuka Ltd
27 West Road, Ohapu
New Zealand
RMP B13

Product of
New Zealand
UMF™
Manuka Honey
Packed under Licence
No. 1040

Best Before:
Batch Number:



NUTRITION INFORMATION		
Servings per package: 12.5		Serving Size: 20g
	Average Quantity per Serving	Average Quantity per 100g
Energy	268kJ	1340kJ
Protein	0.08g	0.4g
Fat, total	0g	0g
- saturated	0g	0g
Carbohydrates	15.9g	79.6g
- sugars	15.6g	78.1g
Sodium	2.4mg	12mg
Ingredients		
100% Pure New Zealand Honey.		
No added ingredients.		
Warning: Honey is not suitable for children under 12 months. Storage Conditions: Store in a cool place.		



UMF™ Manuka Honey - Bee's Inn Honey is produced from areas within New Zealand ranging from lush green farmlands to snow-capped mountains where bees collect the honey from Manuka Tree Flowers. The UMF™ grading system appraises natural markers found in Manuka Honey and assures purity and quality. Please see website www.umf.org.nz

Packed by Bee's Inn Manuka Ltd
27 West Road, Ohaupo
New Zealand
RMP B13

Product of
New Zealand
UMF™
Manuka Honey
Packed under Licence
No. 1040

Bee's Inn



New Zealand Manuka Honey



Net Weight 500g

NUTRITION INFORMATION		
Servings per package: 25		Serving Size: 20g
	Average Quantity per Serving	Average Quantity per 100g
Energy	268kJ	1340kJ
Protein	0.08g	0.4g
Fat, total	0g	0g
- saturated	0g	0g
Carbohydrates	15.9g	79.6g
- sugars	15.6g	78.1g
Sodium	2.4mg	12mg

Ingredients

100% Pure New Zealand Honey.

No added ingredients.

Warning: Honey is not suitable for children under 12 months. Storage Conditions: Store in a cool place.



9 421905 394083 >

Date: _____

Drum No.: _____

Honey Type: _____

Batch: _____

Yard(s): _____

HD _____ **RMP B13**

PRODUCT OF NEW ZEALAND

TUFF BEAR LLC

Foreign Supplier Verification Program

Modified Requirements (Very Small Importer)

1. IMPORTER INFORMATION

IMPORTER's Name: TUFF BEAR LLC	
IMPORTER's Address: 1013 N 3rd Ave Wausau, WI 54401, United States	
Phone Number: 1-608-620-4012	FAX Number: <i>[please provide]</i>
Unique Facility Identifier: <i>[please provide]</i> (DUNS number)	
Qualified Individual: <i>[please provide]</i>	
Company Overview: <i>[Please provide a brief description of the company's operation to include product(s) imported, product distribution, customer profile, number of employees, and a general overview of the import operations.]</i>	
Purpose of the FSVP Plan: The Foreign Supplier Verification Program (FSVP) is the primary document that ensures our foreign suppliers meet established food safety standards. This Foreign Supplier Verification Program has been designed to verify that the food we import is produced in compliance with applicable FDA regulatory requirements and takes into consideration the modified requirements imposed by 21 CFR 1.512 for very small importers. The foreign supplier verification program was developed by a qualified individual.	
Scope of the Foreign Supplier Verification Program: This Foreign Supplier Verification Program addresses the importation of food products creamed honey from Bee's Inn, located at 27 West Road RD 1, Ohaupo, Waikato 3881, New Zealand. The Foreign Supplier Verification Program includes modified requirements as applicable for very small importers. Additionally, the Foreign Supplier Verification Program addresses the need for corrective action and re-evaluation of the FSVP if it is determined that the food is not in compliance with applicable laws and regulations. Lastly, the FSVP addresses the requirement for importer identification at entry.	
Modified Requirements Eligibility Criteria: The calculations for modified requirements eligibility as a very small importer were completed on <i>[please provide]</i> and maintained at Tuff Bear LLC, located at 1013 N 3rd Ave Wausau, WI 54401, United States. A review of the document describing our status as a small importer will be reviewed on an annual basis by December 31 of each calendar year.	

Reviewed by:

Date:

Approved by:

(Owner, operator or agent in charge)

Date:

2. FOREIGN SUPPLIER AND PRODUCT PROFILE

SUPPLIER INFORMATION

Foreign Supplier Name:	Bee's Inn
Manufacturing Address:	27 West Road RD 1, Ohaupo, Waikato 3881, New Zealand
Point of Contact (Name, title and contact information):	Name: <i>[please provide]</i> Title: <i>[please provide]</i> Phone: <i>[please provide]</i> Fax: <i>[please provide]</i> Email: <i>[please provide]</i>
FDA Registration Number:	16802114790
Facility Website:	<i>[please provide]</i>
Number of Full-time Employees:	<i>[please provide]</i>
Facility Size:	<i>[please provide]</i>
Product(s) Imported:	Honey
PCQI (Foreign supplier)	<i>[please provide]</i> <i>[We recommend you request PCQI certificate or appropriate documents to support qualifications based on education, training and experience.]</i>
Foreign Supplier Status (Obtain written assurance that the foreign supplier meets the eligibility criteria):	See section 4 (Foreign Supplier Written Assurance Status)

*The regulation requires that an individual functioning as the PCQI successfully complete training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. It may not be certain whether a particular individual is "otherwise qualified through job experience to develop and apply a food safety system"; FDA may disagree with any such determination. Accordingly, we believe it may be prudent to have the designated individual successfully complete the PCQI course.

PRODUCT DESCRIPTION

Product Name:	Creamed Honey	
Product Description:	The Honey is harvested from the hives and transported to the processing facility. <i>[We recommend providing additional information such as bee species and floral source of honey (scientific name and family) from which they pollinate, etc.]</i>	
Chemical & Physical Features:	Chemical composition:	
	Carbohydrates	Consists in approximately 82% of fructose, 38.2% of glucose, and 31% is sucrose, maltose and isomaltose.
	Protein and amino acids	- Honey contains a number of enzymes, including invertase, which converts sucrose to glucose and fructose. - Honey contains eighteen free amino acids.
	Vitamin, Minerals and Antioxidants:	Honey contains: - Vitamins: trace amounts of B vitamins: riboflavin, folic acid, vitamin B6, and Vitamin C, - Minerals: calcium, iron, zinc, potassium, phosphorous, magnesium, selenium, chromium and manganese. - Antioxidants: flavonoids - Honey contains gluconic acid as the main acid, formed by the breakdown of glucose.
	Chemical characteristics	Tolerance
	Pesticide residues:	<i>[please provide]</i>
	Drug residues (antibiotics):	<i>[please provide]</i>
	Heavy metals	<i>[please provide]</i>
	Tutin toxin (derived from a plant)	- Comb honey: 0.01 mg/kg (ppm) - Packed honey: 0.7 mg/kg (ppm)
	Food Additives:	<i>[please provide information if applicable]</i>
	Water activity (aw):	<i>[please provide information if applicable]</i>
	Moisture content:	<i>[please provide information if applicable]</i>
	pH:	<i>[please provide information if applicable]</i>
	Sugar ratio:	<i>[please provide information if applicable]</i>

		<i>applicable/</i>
	Physical characteristics	Parameter
	Appearance	Color: dark brown, light-dark brown, Amber brown. Colors varies by seasons and areas produced.
	Texture	<i>[please provide]</i>
	Smell	<i>[please provide]</i>
	Flavor	<i>[please provide]</i>
Microbiological Profile:	<i>Microbial recount:</i>	<i>Maximum permitted level</i>
	<i>Clostridium botulinum</i>	<i>[please provide]</i>
	<i>Bacillus cereus</i>	<i>[please provide]</i>
Allergens:	No allergens	
Intended Use:	- This product is intended for direct consumption (ready-to-eat). - This product is intended to be used as an ingredient in further processing.	
Intended Consumers:	Warren Pope, Tuff Bear LLC.	
Packaging:	Conforms to current EU and FDA regulations for plastic containers and drums: <i>[We recommend describing the primary and secondary packaging and its materials.]</i> Primary packaging: <i>[please provide]</i> Secondary Packaging: <i>[please provide]</i>	
Shelf Life:	4 to 5 years	
Storage Conditions:	- Store Honey and packaging materials to: - o minimize contamination, opened cartons of packaging materials are reclosed and covered to prevent contamination with dust/filth; and - o damaged packaging that has been disposed - Storage areas are to be kept clean and tidy. - Honey that is not suitable for human consumption or processing, but is suitable for some other purpose must be kept separate and clearly identified and not be a source of contamination to other honey that is intended for human consumption. Discard any raw materials when it is contaminated or shows signs of spoilage. - Export suitable honey must be stored separated from non-export honey. - All drums of honey must be stored in a tidy manner, with properly fitting bungs, to prevent moisture and contaminants entering drums. - Store all full and empty drums on a pallet inside the processing factory. Damaged drums are to be disposed.	
Distribution and transport	- Honey for export is transported on RMP <i>[please include the meaning]</i> registered vehicles only.	

Conditions:	- The product is distributed to the customer in ambient temperature conditions, either maritime or air freight.
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PRODUCT LISTING

Foreign Supplier's Name:	Products:
Bee's Inn	Rewarena Honey
	Manuka Honey UMF 5+
	Manuka Honey UMF 10+
	Manuka Honey UMF 15+
	Manuka Honey UMF 20+

LABELING REVIEW FOR ALLERGENS:

Product:	Label Reviewed:	Allergens Declared:	Date Reviewed:	Signature of QI:
Creamed Honey	<i>[yes or no]</i>	No allergens	<i>[please provide]</i>	<i>[please provide]</i>

4. FOREIGN SUPPLIER VERIFICATION ACTIVITIES:

[As indicated in your FSVP – SOP document, you must obtain written assurance that the food is being produced in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, and is producing the food in compliance with sections 402 and 403(w) of the FD&C Act, if applicable. The following chart needs to be completed once written assurances are obtained for each food imported.]

Date Provided:	Products Covered:	Does the Written Assurance Include a Brief Description of the Processes and Procedures that provide the same level of public health production as described above?	Are Any Corrective Actions Needed?
<i>[Please include the date when the written assurance is provided by the foreign supplier.]</i>	<i>[For Example: Creamed Honey]</i>	<i>[YES or NO] [Please indicate whether the written assurance include the information above]</i>	<i>[YES or NO] [Please describe the corrective action taken]</i>

In accordance with the modified requirements for very small importers (21 CFR 1.512) we approve:

Foreign Supplier:	Approved Food Products:	Approval Date
Bee's Inn	Creamed Honey	<i>[please provide]</i>

Procedures To Ensure Food Are Produced In Compliance with the Written Assurance:

Responsible Individual: *[please indicate responsible employee]*

Procedure:

1. Verify that each shipment of creamed honey were produced by Bee's Inn, located at 27 West Road RD 1, Ohaupo, Waikato 3881, New Zealand by checking that the written assurance was provided and is current; and the bill of lading and/or the manufacturer's name on the product received.
2. Document foreign supplier's approved status on receiving documents.

Corrections: If we determine that the foreign supplier of food does not produce the food consistent with the assurances the foreign supplier provided in accordance with 21 CFR 1.512; we will promptly determine and document whether we should continue to import the food from the foreign supplier, or discontinue use the foreign supplier, until the cause of adulteration or misbranding has been adequately addressed; and document any information, investigation and corrective actions taken.

Records: Receiving records (e.g., bill of lading) of all imported foods.

Verification: Receiving records reviewed within 7 working days. Document the review.

February 27, 2019

Warren Pope
Tuff Bear LLC
1013 N 3rd Ave
Wausau, WI 54401
United States

RE: Foreign Supplier Verification Program for Honey

Dear Warren Pope:

We present our report with recommendations regarding the development of your modified Foreign Supplier Verification Program (FSVP) Plan for Honey imported by Tuff Bear LLC from Bee's Inn, located at 27 West Road RD 1, Ohaupo, Waikato 3881, New Zealand. The recommendations are based on email correspondence, and other documents you provided to Registrar Corp.

Please note that the contents of your FSVP Plan include a written Standard Operating Procedure (SOP) which provides important definitions and states your responsibilities and commitment to following the modified requirements in the FSVP regulation. Once you go through this FSVP Plan, you may submit it to Registrar Corp for a second review. Registrar Corp will review your plan again, at no additional cost to you, as long as the revised plan is received within 45 days of this letter. You will also notice we placed a **[bracket]** to highlight the need for additional information/clarification in the attached FSVP Plan.

Lastly, your FSVP Plan is a record subject to the modified requirements of Foreign Supplier Verification Programs for Food Importers (21 CFR Part 1, Subpart L). The FSVP regulation in 21 CFR 1.512(b)(5)(i) requires the FSVP importer to sign and date the FSVP and records: (a) upon initial completion; and (b) upon any modification. For your convenience, we have provided a signature/date location on the first page of your FSVP plan.

Our recommendations are outlined in the following pages. Please feel free to contact us via email or phone, after you have reviewed these materials, to discuss any questions or concerns.

Very truly yours,

//Original Signed//
Iris Torres
Regulatory Specialist
Phone: +1-757-224-0177 ext. 536
Email: itorres@registrarcorp.com

I. OBSERVATIONS:

The Foreign Supplier Verification Program (FSVP) regulation for importers found in 21 CFR 1.500 through 1.514 is about ensuring that imported foods meet the same level of public health protection as is required by the Current Good Manufacturing Practice, Hazard Analysis and Risk-based Preventive Controls for Human Food regulation (21 CFR 117) and the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR 507), and to ensure that the supplier's food is not adulterated and is not misbranded with respect to food allergen labeling, as applicable. The U.S. Importers are required to develop, maintain and follow an FSVP for each food brought into the United States and the foreign supplier of that food.

The FSVP Importer is the owner or consignee of an article of food that is being offered for import into the United States. If there is no owner or consignee at the time of entry of the food into the U.S., the FSVP Importer is the U.S. Agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under the FSVP regulation.

The FSVP regulation includes modified requirements for very small importers (VSIs); and importers of food from certain small foreign suppliers. The FSVP rule states that a "very small importer" is an importer averaging less \$1 million U.S. (for human food importers) or \$2.5 million U.S. (for animal food importers) per year in sales of food combine with the U.S. market value of food imported, processed, or held without sale, during the previous 3-years (21 CFR 1.501). Modified requirements also apply if the FSVP importer is importing food from foreign supplier(s) in countries with food safety systems recognized by FDA, or if the FSVP importer is importing dietary supplements or dietary supplement components.

Modified requirements for FSVP (very small) importers are as follows:

- Documentation of Eligibility,
- Use of qualified individuals to conduct FSVP activities,
- Obtaining written assurances from foreign suppliers,
- Discussion of any needed corrective actions, and
- Importer identification for the food offered for entry into the United States
- Re-evaluation of your FSVP either for cause or routinely every 3 years
- Record keeping of all of the above requirements will compose your FSVP

For clarity, 21 CFR 1.512(b) provides more detail information regarding the applicable and additional requirements (21 CFR 1.502, 1.503 and 1.509) in accordance with a modified FSVP program.

Although FSVP requirements apply to most imported food under FDA's regulatory jurisdiction, certain categories of imported food are not covered under the FSVP regulation. These exemptions include certain juice, fish, and fishery products (which are already subject to verification under FDA's hazard analysis and critical control point (HACCP) regulations

for those products), food for research or evaluation, food for personal consumption, alcoholic beverages, food that is transshipped, food imported for processing and future export, food exported from and returned to the United States without manufacturing/processing in a foreign country, and certain meat, poultry, and egg products regulated by the U.S. Department of Agriculture (USDA).

Please note that there is no standardized or required format for a FSVP. You may organize the required information in a manner that suits your systems, the needs of your customers, and the requirements of the regulations. However, we recommend you have a FSVP that is easy to understand, implement and manage; that it is kept up to date; and that it is organized and accessible for inspection.

A. FSVP Importer Information:

We recommend including general information describing your importing operation in your FSVP document. Some of the information below may not be required for compliance with the FSVP regulation but may be useful for organizing the plan and explaining its organization to others:

- Contact information
- Unique Facility Identifier (e.g. DUNS number)
- Name of the qualified individual assigned to conduct FSVP responsibilities
- Company Overview
- Purpose and scope of the FSVP

As previously stated, FSVP activities must be conducted by a qualified individual. A qualified individual as defined by the FSVP regulation (21 CFR 1.500-1.514) means a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under this subpart, and can read and understand the language of any records that the person must review in performing this activity. A qualified individual may be, but is not required to be, an employee of the importer. A government employee, including a foreign government employee, may be a qualified individual.

Documentation of Eligibility Requirements for Very Small Importers Subject to Modified Requirements:

As a very small importer (VSI), you are required to document that (1) you meet the definition of a VSI (21 CFR 1.500) with respect of human or animal food, and (2) you must document the eligibility for VSIs status with respect of human or animal food, before initially importing food, and annually thereafter on an annual basis by the end (December 31th) of an each calendar year (21 CFR 1.512(b)(1)(i)(A)).

If you meet the eligibility requirements for a very small importer, you must have the additional requirements:

- A foreign supplier verification program (as required in 21 CFR 1.502),

- A qualified individual that develops your FSVP and perform FSVP activities (21 CFR 1.503),
 - Identification as the importer of the food (for each line entry) when filing the entry with CBP (as required in 21 CFR 1.509)
- Please review the attached FSVP Plan (Importer Information) for specific details.

B. Foreign Supplier and Product Profile:

We recommend including essential information about your foreign supplier and a detailed description of the product in your FSVP document. Understanding your supplier's operation will help you determine the applicable regulations, their compliance, and the extent of your responsibilities as the FSVP importer.

Understanding basic information about the product, its distribution, as well as information on consumers and intended use is important in identifying potential food safety hazards that need to be addressed by preventive controls.

- Please review the attached FSVP Plan (Foreign Supplier and Product Profile) for specific details.

C. Foreign Supplier Verification Activities

Very Small Importers must establish a foreign supplier verification program for each food to be imported from each of your foreign suppliers (21 CFR 1.502 (a)); under the modified requirements, very small importers are not required to conduct hazard analyses nor evaluate the food and foreign supplier performance (21 CFR 1.512), or conduct evaluation of a foreign supplier's performance and the risk posed by a food or foreign supplier's approval (21 CFR 1.505).

For very small importers, FSVP activities consist in obtaining written assurances from the suppliers.

Written assurances must be obtained, before importing the food and at least every 2 years thereafter, to ensure the foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, and the implementing regulations on preventive controls or produce safety, respectively, and is producing the food in compliance with sections 402 and 403(w) (if applicable) of the FD&C Act (21 CFR 1.512(b)(3)(i)). Importers should request that their foreign suppliers provide assurance on a company letterhead or in a manner that clearly identifies the supplier, the particular food addressed in the assurance, and the applicable FDA food safety requirements. The assurance from the foreign supplier should be dated and include the printed name and signature of an authorizing official.

Corrective Actions:

The importer is responsible for taking appropriate corrective actions when the foreign supplier:

- Does not produce food in compliance with the processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act (21 U.S.C. 350g or 350h), if either is applicable, and the implementing regulations, or
- Produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the FD&C Act (21 U.S.C. 342 and 343(w)). (Section 403(w), regarding misbranding due to failure to provide labeling for the presence of major food allergens, does not apply to animal food.)

If the written assurances are invalid, appropriate corrective actions will depend on the circumstances; however, it could include discontinuing use of the foreign supplier until the cause of adulteration or misbranding has been adequately addressed.

- Please note that the modified requirements in FSVP regulation does not require the approval of foreign suppliers, however we recommended approving the foreign suppliers initially to ensure the written assurances provided by the supplier are valid, and that the food to be imported is produced in compliance with the written assurances and in accordance to FDA requirements.
- The processing of honey is associated with the following food safety hazards:
 - *Biological hazards* such as pathogenic bacteria such as *Bacillus cereus* and *Clostridium botulinum* previously introduced in raw materials or during processing due to lacks of controls.
 - *Chemical hazards* such as presence of heavy metals, pesticide residues, drug residues and plant-originated toxins (specific to the harvest area and the floral source) introduced from received materials.
 - *Physical hazards* such as inclusion of metal fragments from plant environment.
- We recommend ensuring that the written assurance provided by the foreign supplier, address the following steps as appropriate preventive controls to significantly minimize or prevent potential process-related food safety hazards.
 - Bee's Inn identifies in their HACCP Application document that pathogenic bacteria such as *Clostridium botulinum* and its spores is a potential ingredient-related food safety hazard. However, no control has been implemented. We understand that the manufacturer needs to implement a preventive control appropriate to their practices in accordance to Preventive Control for Human Food (PCHF) regulation. We feel that a Supply-Chain Preventive Control is a proper control measure to prevent this hazard

in the raw materials. Also, the implementation of sanitation preventive controls is adequate to prevent cross-contamination of pathogens from the plant environment during the processing of the product.

- Bee's Inn identifies the Receiving step as a CCP for chemical hazards. We agree with this determination. However, we understand that the Receiving step should be designated as a Supply-Chain Preventive Control to prevent the presence of unapproved pesticide residues and drug residues, heavy metals, and plant-originated toxins (e.g. tutin). Bee's Inn verifies Harvester Declaration for each batch to ensure that the received honey meets the specifications. Also, the foreign supplier conducts sampling as their verification activity.
- Bee's Inn processing includes a "Filtering" step during the processing of liquid and creamed honey. However, the firm's hazard analysis did not identify physical contaminants such as foreign objects as potential process-related food safety hazards. Please note that physical contaminants can be introduced during processing from the plant environment. Bee's Inn needs to ensure they have implemented proper controls to prevent this hazard.
- Please review the attached FSVP Plan (Foreign Supplier Verification Activities) for specific details.

D. FSVP Importer identification

The FSVP importer must ensure they are identified at entry for each line of entry of food product offered for importation into the United States, by providing their name, email address, and unique facility identifier (UFI) recognized as acceptable by FDA (e.g. DUNS number). The FSVP importer information must be provided to the filer/broker in charge of submitting your food to CBP (U.S. Customs and Border Protection).

E. Recordkeeping

You must keep original records, true copies, or electronic records to support your FSVP for each food from a particular foreign supplier (21 CFR 1.512(b)(5)). Electronic records are recommended (not required) by FDA as they can be more easily retrieved and searched.

FSVP records must be signed and dated upon initial completion and upon any modification of the FSVP (21 CFR 1.512(b)(5)). These include the following records: written assurances and corrective actions, etc. All records must be available promptly to an authorized FDA representative, upon request, for inspection and copying. All FSVP records must be legible and stored to prevent deterioration or loss and must be kept for at least 2 years after they were created or obtained. In addition, reliable records that supports the status of a very small importer during the 3-year period preceding the applicable calendar year, must be retained for at least 3-years (21 CFR 1.512(b)(5)(iii)).

Additionally, you must maintain records and documentation that demonstrate your compliance with applicable FSVP requirements as a very small importer.

F. Standard Operating Procedure

The Standard Operating Procedure (SOP) specifies the activities necessary to meet the FSVP requirements as required in 21 CFR Part1, Subpart L- Foreign Supplier Verification Programs for Food Importers including programs to ensure that the imported food is produced in accordance to the FDA regulatory requirements explained throughout this cover letter. It will also serve as proof of your commitment to following the FSVP regulations requirements.

Disclaimer

Certain components of our Foreign Supplier Verification Program Plan Services are necessarily subjective. Our recommendations constitute our advice concerning prudent compliance with FDA regulations, where one exists for the product category and production process, and do not constitute a guarantee of acceptance by the U.S. Food and Drug Administration. You can use alternate approach if the approach satisfies the requirements of the applicable statutes and regulations. Registrar Corp does not offer legal advice and is not responsible for any actual, incidental or consequential damages. For a legal opinion concerning construction or application of the regulations or statutes, we recommend retaining an attorney.

Foreign Supplier Verification Plan

Standard Operating Procedure

(Very Small Importer)

1. IMPORTER INFORMATION

IMPORTER's Name: TUFF BEAR LLC	
IMPORTER's Address: 1013 N 3rd Ave Wausau, WI 54401, United States	
E-mail Address: <i>[insert information]</i>	
Phone Number: 1-608-620-4012	Fax Number: <i>[please provide]</i>
Unique Facility Identifier: <i>[please provide]</i> (DUNS number)	

- **Purpose** - This SOP specifies the activities necessary to meet the FSVP modified requirements as required in 21 CFR Part 1 (Subpart L – Foreign Supplier Verification Programs for Food Importers) including programs to ensure that the imported food is:
 - Produced in a manner that provides the same level of public health protection as required under section 418 or 419 of the FD&C Act, as appropriate
 - Is not adulterated under section 402 of the FD&C Act
 - Is not misbranded under section 403(w) of the FD&C Act
- **Scope** - This SOP applies to all food imported or offered for import into the United States with the following exemptions:
 - Juice and seafood products subject to and in compliance with FDA's Hazard Analysis and Critical Control Point (HACCP) regulation
 - Food for research and evaluation
 - Food for personal consumption
 - Alcoholic beverages
 - Food that is imported for processing and future export
 - Certain meat, poultry and egg products regulated by the United States Department of Agriculture at the time of importation
- **Definitions** – The following definitions are applicable to this SOP
 - Facility – A domestic facility or foreign facility that is required to register under section 415 of the FD&C Act
 - Foreign Supplier – The establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a minimal nature.
 - Hazard – Any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury.

- **Importer** – The U.S. owner or consignee of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer.
- **Qualified individual** – A person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under the FSVP regulation, and can read and understand the language of any records that the person must review in performing this activity. A qualified individual may be, but is not required to be, an employee of the importer. A government employee, including a foreign government employee, may be a qualified individual.
- **U.S. owner or consignee** - The person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.
- **Very small importer** - (1) With respect to the importation of human food, an importer (including any subsidiaries and affiliates) averaging less than \$1 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of human food combined with the U.S. market value of human food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee); and (2) With respect to the importation of animal food, an importer (including any subsidiaries and affiliates) averaging less than \$2.5 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of animal food combined with the U.S. market value of animal food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee).
- **Responsibilities** - It is the responsibility of TUFF BEAR LLC personnel to understand and comply with this SOP. Importers are required to develop, maintain and follow an FSVP for each food brought into the United States and the foreign supplier of that food. Very Small Importers are responsible for actions that include:
 - Documenting eligibility and Very Small Importer status
 - Conducting supplier verification activities
 - Conducting corrective actions
 - Providing the importer identification number (e.g., DUNS) for each line entry of food that is imported
- **Recordkeeping and FDA Access** – All records related to the FSVP SOP will be kept for a minimum of 2 years after they were created or obtained. Records related to processes and procedures will be kept for a minimum of 2 years after their use is discontinued. Upon request, records will be made available to FDA for inspection and copying. If necessary, an English translation of the records will be provided within a reasonable timeframe.

Procedure

In compliance with the **FSVP SOP**:

- Eligibility criteria for modified requirements (as a Very Small Importer).
 - Documentation of eligibility: TUFF BEAR LLC must document that they meet the definition of a “very small importer”, averaging less \$1 million U.S. (for human food importers) or \$2.5 million U.S. (for animal food importers) per year in sales of food combine with the U.S, during a relevant 3-years period of sales before initially importing food as a “very small importer”, and annually thereafter by December 31 of each calendar year.
 - Additional Requirements: TUFF BEAR LLC must: (1) use a qualified individual for each FSVP verification activity; (2) be identified as an importer of the food when filing the entry with CBP; and (3) obtain written assurance from the foreign suppliers.
- Importer Identification Number. TUFF BEAR LLC will have a unique facility identifier (e.g., DUNS) that is acceptable to FDA for each line entry of food that is imported.
- Foreign Supplier Verification. TUFF BEAR LLC will obtain from the foreign supplier, a written assurance to ensure:
 - the food is being produced in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable; and
 - the food is in compliance with FD&C Act adulteration provisions and for human food allergen labeling provisions.

These assurances need to be obtained before importing the food and every 2 years thereafter; and must be obtained for every food to be imported from the foreign supplier. The written assurance from the foreign supplier should be dated and include the printed name and signature of an authorizing official.

- Corrective Actions. TUFF BEAR LLC will take prompt corrective actions if it determines that a foreign supplier does not produce food consistent with the written assurance, and in compliance with applicable processes and procedures that provide same level of protection as FDA requirements. If TUFF BEAR LLC determines by means other than verification activities that a foreign supplier does not produce food in compliance with applicable processes and procedures that provide the same level of protection as FDA requirements, we will conduct an investigation to determine whether the FSVP needs to be modified. Such corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed.
- Importer Identification. TUFF BEAR LLC will ensure that, for each line entry, the following information is provided to U.S. Customs and Border Protection:
 - Importer’s name;
 - Importer’s email address; and
 - A unique facility identifier acceptable to FDA

- Record Review. TUFF BEAR LLC will ensure that a qualified individual signs and date records concerning the FSVP upon initial completion and upon any modification of the FSVP.

Reviewed by:
(Qualified Individual)

Date:

Approved by:

Date:



CERTIFICATE OF REGISTRATION

This certifies that:

Bees Inn
27 West Road RD 1
Ohaupo, Waikato 3881
New Zealand

is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as currently effective on the date hereof by Registrar Corp:

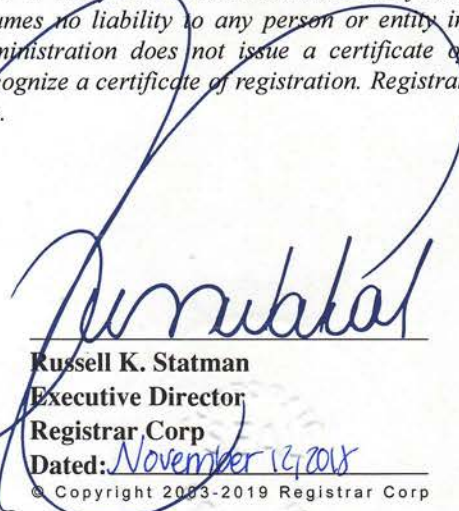
U.S. FDA Registration No.: **16802114790**

U.S. Agent for FDA
Communications: **Registrar Corp**
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

This certificate affirms that the above stated facility is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as effective by Registrar Corp as of the date hereof, and Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until December 31, 2019, unless such registration has been terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp ★

144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com



Russell K. Statman
Executive Director
Registrar Corp

Dated: November 14, 2018

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FDA | U.S. Food and Drug Administration

Food Facility Registration

Date: 02/19/2019 10:26:31

Please review the registration.

Created Date

2018-07-10 12:23:13.0

Created by

reg79386

Registration Expiration Date

2020-12-31

Registration Renewed Date

2018-11-12

Last Updated

2018-11-12

Last Modified by

reg56562

Last Modified by Company

Bees Inn

Registration Status

VALID

Is this facility engaged in the manufacturing/processing, packing, or holding of food for human or animal consumption in the United States?

☒ Yes ☐ No

Section 1: Type of Registration

Facility Location: **Foreign Registration**

FACILITY REGISTRATION NUMBER **16802114790**

Are you the new owner of a previously registered facility?

☐ Yes ☒ No

Previous Owner's Title:

Previous Owner's Name:

Previous Owner's Registration Number:

Section 2: Facility Name/Address Information

Facility Name

Bees Inn

Telephone Number

064 7 8236513

Facility Name Suffix

Other

Fax Number

E-Mail Address

dave-west@xtra.co.nz

Facility Name Suffix Other

Partnership

Facility Street Address, Line 1

27 West Road

Facility Street Address, Line 2

Rd 1

City

Ohaupo

State/Province/Territory

Waikato

Zip/Postal Code

3881

Country/Area

NEW ZEALAND

Section 3: Preferred Mailing Address Information

Complete this section if different from Section 2 Facility Name/Address Information (OPTIONAL)

Is the preferred mailing address the same as the facility address (Section 2)? No

Name

Bees Inn Manuka Ltd

Telephone Number

064

Address, Line 1

NZ Post Centre

Fax Number

Address, Line 2

106A Great South Road

E-Mail Address

City

Ohaupo

State/Province/Territory

Waikato

Zip Code (Postal Code)

3881

Country/Area

NEW ZEALAND

Section 4: Parent Company Name/Address Information

(If applicable and if different from Sections 2 and 3). If information is the same as another section, check which section:

- ☒ Same as Facility Address (Section 2)
☐ Same as Preferred Mailing Address (Section 3)
☐ None of the above

Company Name

Bees Inn

Telephone Number

064 7 8236513

Company Name Suffix

Other

Fax Number

Company Name Suffix Other

Partnership

E-Mail Address

dave-west@xtra.co.nz

Address, Line 1

27 West Road

Address, Line 2

Rd 1

City

Ohaupo

State/Province/Territory

Waikato

Zip Code (Postal Code)

3881

Country/Area

NEW ZEALAND

Section 5: Facility Emergency Contact Information

If information is the same as another section, check which section:

- ☐ Same as Facility Address (Section 2)
☐ Same as U.S. Agent Information (Section 7)
☒ None of the above

Individual's Title *(Optional)*

Mr

Emergency Contact Phone

001 608 6204012

Individual's Name *(Optional)*

Warren

E-mail Address

sales@tuffbear.com

Individual's Middle Name *(Optional)*

Job Title *(Optional)*

Co-Partner

Individual's Last Name *(Optional)*

Pope

Section 6: Trade Names

(If this facility uses trade names other than that listed in Section 2 above, list them below (e.g., "Also doing business as," "Facility also known as"))

Are there alternate trade names used by your facility in addition to the name provided in **Section 2: Facility Name/Address Information?**

- ☐ Yes ☒ No

Section 7: United States Agent

(To be completed by facilities located outside any state or territory of the United States, District of Columbia, or The Commonwealth of Puerto Rico)

Name

Registrar Corp

Telephone Number

757 2240177

Address, Line 1

144 Research Dr

Emergency Contact Phone

802 3728842

Address, Line 2

Fax Number

757 2240179

City

Hampton

E-Mail Address

info@registrarcorp.com

State/Province/Territory

Virginia

Zip Code (Postal Code)

23666-1339

Country/Area

UNITED STATES

Section 8: Seasonal Facility Dates of Operation *(Optional)*

Give the approximate dates that your facility is open for business, if its operations are on a seasonal basis *(Optional)*.

Harvest 1

Start Month

End Month

Harvest 2

Start Month

End Month

Section 9: General Product Categories - Human/Animal/Both

☒ Food for Human Consumption

☐ Food for Animal Consumption

Section 9a: General Product Categories - Food for Human Consumption; and Type of Activity Conducted at the Facility

To be completed by all food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 37.	Ambient Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators)	Refrigerated Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks)	Frozen Food Storage Warehouse / Holding Facility (e.g., storage facilities)	Acidified Food Processor	Low-Acid Food Processor	Interstate Conveyance Caterer / Catering Point	Contract Sterilizer	Labeler / Relabeler	Manufacturer / Processor	Packer / Repacker	Salvage Operator (Reconditioner)	Farm Mixed-Type Facility	Other Activity Conducted (Please Specify)
37. IF NONE OF THE ABOVE FOOD CATEGORIES APPLY, THEN PRINT THE APPLICABLE FOOD CATEGORY OR CATEGORIES (THAT DOES NOT OR DO NOT APPEAR ABOVE)	☒	☐	☐	☐	☐	☐	☐	☐	☒	☐	☐	☐	☐
If the food categories listed above do not apply, then print the applicable food category or categories.													
Honey													

Section 10: Owner, Operator, or Agent-in-Charge Information

Provide the following information, if different from all other sections on the form. If information is the same as another section of the form, check which section:

If information is the same as Section 2, check the box:

- ☒ Section 2 - Facility Address Information
☐ Section 3 - Preferred Mailing Address Information
☐ Section 4 - Parent Company Address Information
☐ Section 7 - US Agent Address Information
☐ None of the above

Name of Entity or Individual Who is the Owner, Operator, or Agent-in-Charge: Samuel David West

Address, Line 1
27 West Road

Telephone Number
064 7 8236513

Address, Line 2
Rd 1

Fax Number

City
Ohaupo

E-Mail Address
dave-west@xtra.co.nz

State/Province/Territory
Waikato

Zip Code (Postal Code)
3881

Country/Area
NEW ZEALAND

Section 11: Inspection Statement

☒ FDA will be permitted to inspect the facility at the time and in the manner permitted by the Federal Food, Drug, and Cosmetic Act.

Section 12: Certification Statement

The owner, operator, or agent-in-charge of the facility, or an individual authorized by the owner, operator, or agent-in-charge of the facility, must submit this form. By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent-in-charge of the facility certifies that the above information is true and accurate. An individual (other than the owner, operator or agent-in-charge of the facility) who submits the form to the FDA also certifies that the above information submitted is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent-in-charge must below identify by name the individual who authorized submission of the registration. Under 18 U.S.C 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

NAME OF PERSON SUBMITTING THIS REGISTRATION FORM: Mary Hancock, an employee of Registrar Corp.

CHECK ONE BOX

- ☐ A. INDIVIDUAL ASSOCIATED WITH THE INFORMATION IN SECTION 10 (STOP HERE, FORM IS COMPLETED)
- ☒ B. ANOTHER AUTHORIZED INDIVIDUAL

Address Information for the Authorizing Individual:

- ☒ Same as Section 10

Individual's Name
Samuel David West

Telephone Number
064 7 8236513

Address, Line 1
27 West Road

Fax Number

Address, Line 2
Rd 1

E-Mail Address
dave-west@xtra.co.nz

City
Ohaupo

State/Province/Territory
Waikato

Zip Code (Postal Code)
3881

Country/Area
NEW ZEALAND

Warning Letters

Learn about the types of warning letters on FDA's website.

(/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters)

- Matters described in FDA warning letters may have been subject to subsequent interaction between FDA and the letter recipient that may have changed the regulatory status of issues discussed in the letter.
- To obtain additional available information, contact FDA. Requests to FDA for agency records should be sent to: Food and Drug Administration Division of Freedom of Information (HFI-35), 5630 Fishers Lane, Rockville, MD 20857. Instructions for how to submit an FOI request can be found at How to Make a FOIA Request. (/how-make-foia-request)

Search

Showing 0 to 0 of 0 entries (filtered from 2,884 total entries)

Filters

Issuing Office

Letter Issue Date

Letters with Response or Closeout

Posted Date

Year

Clear Filters

Show entries

Export Excel

Posted Date	Letter Issue Date	Company Name	Issuing Office	Subject	Response Letter	Closeout Letter
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No matching records found

Showing 0 to 0 of 0 entries (filtered from 2,884 total entries)

Previous

Next