

United States Department of Agriculture

Agricultural Marketing Service, Specialty Crops Program, Specialty Crops Inspection Division

PATCH # 099

DOCUMENT: Certification of Honey and Apiculture Products Destined for the European Union (EU)

REMARKS: Changes in EU model certificate statements obsolete the current Appendix IV example of the SC-144 and associated guidance for completion on page 3. A revised SC-144 is available on the AMS Forms Catalog at the following Intranet link: SC-144.pdf. The revised SC-144 includes guidance for completion of the SC-144 as additional pages within the PDF.

This PATCH represents official guidance. This PATCH is scheduled to be incorporated into the document listed above. After incorporation into the document listed above this PATCH will become obsolete. USDA is an equal opportunity provider, employer, and lender.



United States Department of Agriculture

Agricultural Marketing Service, Specialty Crops Program, Specialty Crops Inspection Division

CERTIFICATION OF HONEY AND APICULTURE PRODUCTS DESTINED FOR THE EUROPEAN UNION (EU)

PURPOSE

This instruction is designed for Specialty Crops Inspection (SCI) Division employees of the U.S. Department of Agriculture (USDA). Its purpose is to assist in the uniform certification of products destined for the European Union (EU). These procedures are an integral part of Division services. If needed, contact your immediate supervisor for any situation not addressed in this instruction.

BACKGROUND

The EU requires that the honey and apiculture products being certified are produced in an establishment(s) that implements a program based on Hazard Analysis and Critical Control Points (HACCP) in accordance with Regulation (EC) No 852/2004 and that the product(s) have been handled and where appropriate, prepared, packaged, and stored in a hygienic manner in accordance with the requirements of Annex II to Regulation (EC) No 852/2004 (these regulations can be downloaded from the following link:

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0852R(01)&from=EN).

POLICY

Because of the above requirements, the establishment must have an acceptable HACCP program and pass a SCI Plant Survey before it can produce product for EU certification.

- A. SCI will perform the Plant Survey and HACCP audits.
- B. After the requirements are met, the establishment will proceed with production.
- C. SCI will perform a lot inspection.
- D. Product grading would be based on organoleptic, flavor, odor, and foreign material and any additional analytical requirements.
- E. Product evaluation is based on actual time.

PROCEDURES

Once an establishment has passed the Plant Survey with the HACCP audit, the applicant will need to request a lot inspection each time an EU certification is needed. When an applicant has

Effective Date: April 2021 Page 2 of 10

requested an EU certification on a lot of product, an inspector (or licensed sampler) will travel to the establishment to draw samples for evaluation and analytical testing.

When the inspector/sampler arrives, a "walkthrough" of the establishment will be performed to verify that the location still meets sanitation/HACCP conditions. If problems are noted, the inspector/sampler will contact the Officer-in-Charge (OIC) before proceeding. If the establishment is acceptable, the inspector/sampler will proceed to sample the product as requested.

For the EU certification, the inspector/sampler will draw three (3) samples of the product. Each sample must contain at least five (5) pounds of product. These samples will be transported back to the office to be used for both product examination and for analytical testing.

The product will be evaluated using organoleptic means for flavor, odor, and foreign material. If the product is found to be acceptable, a composite sample shall be made for analytical testing. The composite sample shall be six (6) pounds. The composite shall be divided into six equal portions (one pound each) and shall be packed into leak-proof sterile sample collection bags (such as Whirl-Pak® sampling bags). Three (3) of the sample bags will be sent for analytical testing and three (3) bags will be retained as reserve samples. The reserve samples can be used if a retest is requested or if the original samples are lost in transit.

Prepare a form SC-637 Laboratory Sample Submittal Sheet for submitting samples for analytical testing. The samples shall be sent to the following address:

Intertek Food Services GmbH Me Sabine Engel Olof-Palme-Str. 8 Sample Registration & Orders Food 28719 BREMEN Germany

Telephone: 49042165727328

The samples shall be tested for the following:

Chloramphenicol by ELISA-Test (11013010)
Metronidazole by LC-MS/MS (11010890)
Nitrofurane Metabolites by LC-MS/MS (11010110)
Streptomycin by LC-MS/MS (11010820)
Sulfonamides and Trimethoprirn by LC-MS/MS (11010870)
Tetracyclines by LC-MS/MS (11010091)
Pesticides by GC and LC-MS (11011480)

See Appendix I for an example of a completed SC-637. Note that because the list of tests being requested it too large to fit in the block on the form, the list of tests is included as an attachment to the SC-637. See Appendix II for an example of a completed attachment.

Effective Date: April 2021 Page 3 of 10

In the event that the product sampled violates lab test results, please contact the following:

- Charlotte Liang (Charlotte.Liang@fda.hhs.gov), CFSAN, Office of Food Safety
- Standra Purnell (Standra.Purnell@fda.hhs.gov), CFSAN, Office of Compliance

PRODUCT CERTIFICATION

First, certify the product using an SC-146 (Certificate of Quality and Condition). See Appendix III for an example of a completed SC-146E.

NOTE: If this is a corrected certificate, there is a 1-line space (just below the space for the office address) to enter the term "CORRECTED CERTIFICATE" (all caps). Additionally, if this is a corrected certificate, in the remarks section of page 2 (below the inspector's signature and date), enter the statement "THIS CERTIFICATE SUPERSEDES CERTIFICATE NUMBER ______" to identify the certificate being superseded.

Form SC-144 Health Certificate for Export of Apiculture Products Intended for Human Consumption from the United States to the European Union is used to certify the product for the EU program. This form can be found on the AMS Forms Catalog at the following intranet address: http://agnis/AMSFormsCatalog/Forms/AllItems.aspx. See Appendix IV for an example of a completed SC-144.

Most information on page one of the SC-144 is to be completed by the applicant. This can be done by sending the SC-144 PDF to the applicant via email. Instruct the applicant to only complete page 1, Part I: Details of Dispatched Consignment, the applicant will need to complete all of the sections except I.2. "Certificate Reference Number." The applicant will return the form back to the office for completion.

The office will complete page 1 by entering the certificate number from the completed SC-146 into the "Certificate Reference Number" block and their office address in the upper right corner. Complete page 2 by placing an "X" in front of each of the three statements to indicate compliance with the requirements. Enter the statement "Capital X means compliance" in the notes section. The bottom of page 2 requires the inspector's name, title, signature, and the date. Remember to type the inspector's name in ALL CAPITALS.

The SC-144 needs to be stamped with the USDA "Officially Sampled" stamp. This is done on the right-hand side of the page across from the inspector's signature. The EU requires that we stamp the certificate with **blue** ink. Some receiving countries may require that we stamp and sign both pages of the certificate. It is the applicant's responsibility to inform us when this additional requirement is requested.

Once completed the original SC-144 is issued to the applicant. A copy of the SC-144, the original SC-637 and SC-146(E) are filed in the product folder within the office.

Effective Date: April 2021 Page 4 of 10

The SC-144 must be issued before the consignment to which it relates leaves the control of the competent authority of the country of dispatch. This means that the SC-144 must be issued after all the products in the consignment have been produced, but **before** the consignment leaves the country, ideally when the product leaves the dispatch establishment. This is because the original SC-144 must accompany consignments on entry into the EU.

Previously Certified Bulk Lots

If a portion of a previously certified lot is destined for the European Union that will use all the grade and quality factor information from the original lot, a "Breakdown" certificate may be issued. At times, it may be of benefit to the applicant to certify a bulk load or lot using a breakdown certificate for Honey and other Apiculture products destined for the European Union. The procedures for preparing a breakdown certificate are outlined in the Certification Manual. To promote transparency in commerce between the United States and the European Union, it is important that inspectors utilize the following statement when completing SC-144 breakdown certificates.

Statement to be placed on the SC-144 underneath the date on page 2:

"This certificate covers a portion of (lot number) which consisted of (originally sampled lot size cases/bins/jars/drums, etc.) that was previously inspected and certified on (Inspection certificate number) dated (XX/XX/XXXX)."

BILLING

The applicant is billed for actual driving, sampling, and grading time plus 1 hour for certification. This is 1/2 hour for each certificate utilized for each EU certification (SC-146 and SC-144).

Effective Date: April 2021 Page 5 of 10

APPENDIX I – SC-637

Electronic version of SC-637 (Intranet link)

U.S DEPARTMENT OF AGRICULTURE AGRICULTURAL MARKETING SERVICE SPECIALTY CROPS PROGRAM LABORATORY SAMPLE SUBMITTAL SHEET		To MS Sabine Engel Sample Registration & Orders Food Service Intertek Food Services GmbH Bremen, Germany		
APPLICANT ABC Honeymaker, Inc. 123 Main Street Anytown, WI 12345		FROM USDA, AMS, SCP Specialty Crops Inspection Division 2490 Enterprise Drive Oshkosh, WI 54904		
RECEIVER		NO. OF SAMPLES		
Sarant Ltd. 4th Floor, 30-34 Curtain Road London. Ec2A 3NZ Grobbritannien (UK)		☐ Individual ☐ Individual to be composited ☐ Reserve ☐ Reserve		
PRODUCT	TYPE	5	STYLE	
DRIED HONEY	Dried	F	ree Flowing	
ANALYSIS REQUESTED See Attachment	4			
CONTRACT NO.	LOT NO.	3456	SAMPLE NO 0001	
SPECIFICATION AND AMENDMENT	EFFECTIVE DATE	NO. AND TYPE O 240 - 50 lb. Corruga NO. OF POUNDS	F CASES ted Cardboard Cartons 12000	
RESULTS AND BILLING TO		SUBMITTED BY	(Inspector's Signature - P	
Billing to Receiver - Sarant Ltd. Results: Fax to Oshkosh (920) 232-0341 or email kin.agrader@ams.usda.gov		Kim Agrader	Kim L	Agrader
		DATE SIGNED 03/21/2019		
	TO BE COMPI	LETED BY LAB		
DATE RECEIVED	LAB NO.	CONDITION OF S	SAMPLE	
SHIPPING METHOD				
RESULTS				
*				
Security Tape #: OSH-0001 and OSH-0002				
CHARGES	MEETS FAI	LS (If fails, explain below)		
SUBCENTER NUMBER	ANALYZED BY (Pri	nt and Sign)	DATE SIGNED	

SC-637

Effective Date: April 2021 Page 6 of 10

APPENDIX II – ANALYSIS REQUESTED

Attachment A

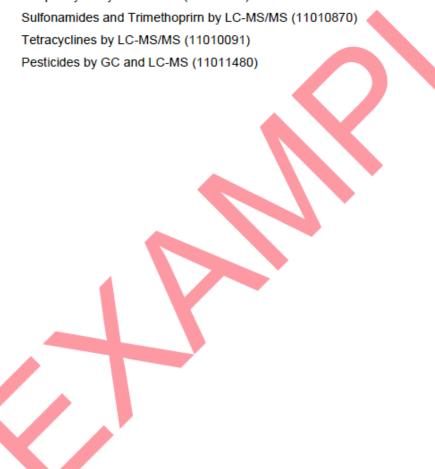
Analysis Requested:

Chloramphenicol by ELISA-Test (11013010)

Metronidazole by LC-MS/MS (11010890)

Nitrofurane Metabolites by LC-MS/MS (11010110)

Streptomycin by LC-MS/MS (11010820)



Effective Date: April 2021 Page 7 of 10

APPENDIX III – SC-146E



UNITED STATES DEPARTMENT OF AGRICULTURE

AGRICULTURAL MARKETING SERVICE

CERTIFICATE OF QUALITY AND CONDITION (PROCESSED FOODS)

This certificate is receivable in all courts of the United States as prima facie evidence of the truth of the statements therein contained. It does not excuse failure to comply with any applicable Federal or State laws.

WARNING: Any person who knowingly falsely make, Issue, alter, forge, or counterfelt this certificate, or participate in any such action, is subject to a fine of not more than \$1,000 or imprisonment for not more than one year, or both (7U.S.C. 1622 (h)).

The conduct of all services and the hiring and licensing of all personnel under the regulations governing such services shall be accomplished without discrimination as to race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status.

Please refer to this certificate by number and inspection office.

A-000000

DATE

March 22, 2019

APPLICANT	ADDRESS
ABC Honeymaker, Inc.	Anytown, WI 12345
RECEIVER OR BUYER	ADDRESS
Sarant	HULL, UNITED KINGDOM
SOURCE OF SAMPLES	PRODUCT INSPECTED
OFFICIALLY DRAWN	FREE FLOWING DRIED HONEY POWDER

CODE MARKS ON CONTAINERS

dhp1234...

PRINCIPAL LABEL MARKS

"ABC DRIED HONEY"

CONDITION: Product was produced in an establishment which meets the requirements of the HAACP principles in accordance with "the relevant provisions of EU Regulations (EC) no. 852/2004."

Grade

Product meets "the relevant provisions of EU Regulations (EC) NO. 852/2004."

Remarks

This certificate covers 240-50 pound corrugated cardboard cartons with 4 mil polyethylene inner bags (12,000 pounds, exporter's count and weight). Lot(s) located at applicant's warehouse at Anytown, Wisconsin, and identified by code mark(s) as shown above. Lot also identified by:
Place of Loading: ABC Honeymaker, Inc. - Anytown, WI 12345 Date of Departure: February 15, 2019
Means of Transport: Ship: Mol Express Entry BIP in EU: Felixstowe, UK
Identification of seal container/seal number: ABCZ123456-4 Seals: 000001
Temperature of product: Ambient

The described product(s) above was (were) produced in an establishment which meets the requirements of the HAACP principles in accordance with "the relevant provisions of EU Regulations (EC) No. 852/2004."

Pursuant to regulations issued by the Secretary of Agriculture under the Agricultural Marketing Act of 1946, as amended (/ U.S.C. 1621-162/), governing the inspection certification of the product designated herein, I certify that the quality and condition of the product shown by samples inspected on the above date were as shown, subject to any restrictions specified above.

ADDRESS OF INSPECTION OFFICE	SIGNATURE OF INSPECTOR
2490 Enterprise Drive,	Kim Agrader
Oshkosh, WI 54904	Kim Agrader

SC-146E

Effective Date: April 2021 Page 8 of 10

APPENDIX IV – SC-144

Electronic version of SC-144 (Intranet link)



OMB No. 0581-0125

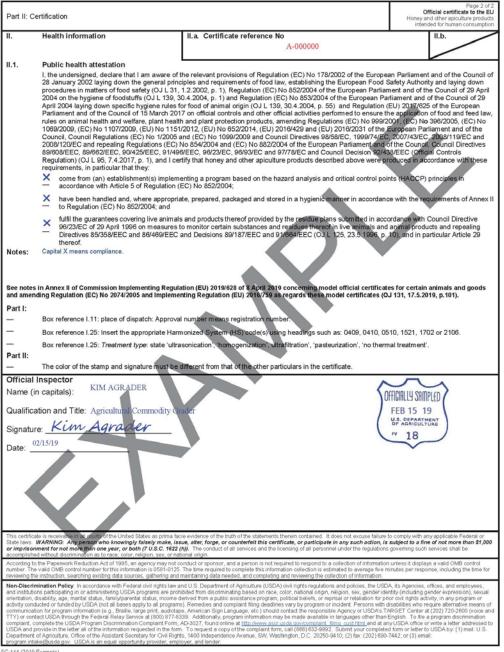
Specialty Crops Inspection Division 2490 Enterprise Drive Oshkosh, WI 54904

AGRICULTURAL MARKETING SERVICE Specially Crops Program Specially Crops Inspection Division CERTIFICATE FOR THE ENTRY INTO THE UNION FOR PLACING ON THE MARKET OF HONEY AND OTHER APICULTURE PRODUCTS INTENDED FOR HUMAN CONSUMPTION

Part I: Details of Dispatched Consignment Page 1 of 2 Official certificate to the EU					
14 Canaignas Expansos			I.2. Certificate Reference Number	1.2 a IMSOC reference No	
I.1. Consignor/Exporter Name ABC Honeymaker, In	c.		A-000000	1.2.a IMSOC reference No	
Address 123 Main Street Anytown, WI 12345			I.3. Central Competent Authority		
Tel. No (123) 466-1234			I.4. Local Competent Authority		
I.5. Consignee/Importer			I.6. Operator responsible for the co	nsignment	
Name Sarant			Name Sarant		
Address Unit 26 Gothenberg Way Sutton Fields Ind. Est Hull United Kingdom			Address Unit 26 Gothenberg Wa Sutton Fields Ind. Est Hull United Kingdom	y	
Postal code HU7 0YN			Postal code HU7 0 YN		
Tel. No +44 1234 123456					
I.7. Country of Origin	ISO Code	1.8.	I.9 Country of Destination ISC	Code I.10.	
United States of America	US		United Kingdom UK		
I.11 Place of dispatch Name ABC Honeymaker, Inc		approval number: 23456	I.12. Place of destination Name Sarant	·	
			The second secon		
123 Main Street Address Anytown, WI 12345			Address Unit 26 Gothenberg Way Sutton Fields Ind. Est Hull United Kingdom		
I.13. Place of Loading			I.14. Date and time of Departure		
ABC Honeymaker, Inc., Anytown	n, WI 12345		2/13/19 2:02 pm		
I.15. Means of Transport Airplane	Vessel 🔀	Other	I.16. Entry BCP Felixstowe, UK		
Road Vehicle	Railway	Still L	I.17. Accompanying documents	OCCUPIAL III DOMOLO	
Identification: Vessel London Express			Туре	OFFICIALLY SAMPLED	
I.18. Transport conditions	-		No.	U.S. DEPARTMENT	
	illed	Frozen 🗆	Kim Agrad	er of AGRICULTURE by 18	
I.19. Container No/Seal No Container # ABC//123456-4 Seal	# 000001				
I.20. Goods certified as					
Human consumption					
l.21.			1.22.		
1.23 Total number of packages	1.24. Quar	ntity Total number	Total net weight (Kg)	Total gross weight (Kg)	
240	240		12,000 pounds	15,000 pounds	
I.25. Description of goods					
No Code and CN title					
2106 Free Flowing Dried Honey	Powder				
Species (Scientific	name)	1	Manufacturing plant	Treatment type	
Apis Mellifera		ABC Honeymaker, Inc.,	Charles and the same of the sa	Heat-treated	
A STATE OF THE PARTY OF THE PAR	umber of packages	FDA#00000000000			
240		Net weight	Batch No	Type of packaging	
240		12,000 pounds	dhp1234	Corrugated	
				Cardboard Cartons	

SC-144 (2019 Example)

Effective Date: April 2021 Page 9 of 10



Effective Date: April 2021 Page 10 of 10

"SCI moving forward in the 21st Century using technology, innovation, and old fashioned hard work"

Non-Discrimination Policy: In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720-2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877-8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD-3027, found online at How to File a Program Discrimination Complaint and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632-9992. Submit your completed form or letter to USDA by: (1) mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW, Washington, D.C. 20250-9410; (2) fax: (202) 690-7442; or (3) email: program.intake@usda.gov.

USDA is an equal opportunity provider, employer, and lender.