



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](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

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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 will be made for analytical testing. The composite sample will be six (6) pounds. The composite will be divided into six equal portions (one pound each) and will 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 will 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 will 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 Trimethoprim 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 is 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.

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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
- Sandra Purnell (Sandra.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, sections I.1,5,7, 9, 11, 13-16, 18-25, 27, and 28. 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.

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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.

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).

APPENDIX I – SC-637

[Electronic version of SC-637](#)

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 Sarant Ltd. 4th Floor, 30-34 Curtain Road London. Ec2A 3NZ Grobbritannien (UK)		NO. OF SAMPLES <input type="checkbox"/> Individual <input type="checkbox"/> Individual to be composited <input checked="" type="checkbox"/> Composite	
		<input checked="" type="checkbox"/> Original <input type="checkbox"/> Reserve	
PRODUCT DRIED HONEY	TYPE Dried	STYLE Free Flowing	
ANALYSIS REQUESTED See Attachment A			
CONTRACT NO.	LOT NO. 123456	SAMPLE NO. 0001	
SPECIFICATION AND AMENDMENT	EFFECTIVE DATE	NO. AND TYPE OF CASES 240 - 50 lb. Corrugated Cardboard Cartons	
		NO. OF POUNDS 12000	
RESULTS AND BILLING TO Billing to Receiver - Sarant Ltd. Results: Fax to Oshkosh (920) 232-0341 or email kin.agrader@ams.usda.gov		SUBMITTED BY (<i>Inspector's Signature - Print and Sign</i>) Kim Agrader <i>Kim Agrader</i>	
		DATE SIGNED 03/21/2019	
TO BE COMPLETED BY LAB			
DATE RECEIVED	LAB NO.	CONDITION OF SAMPLE	
SHIPPING METHOD			
RESULTS			
Security Tape #: OSH-0001 and OSH-0002			
CHARGES	<input type="checkbox"/> MEETS <input type="checkbox"/> FAILS (<i>If fails, explain below</i>)		
SUBCENTER NUMBER	ANALYZED BY (<i>Print and Sign</i>)	DATE SIGNED	

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)
- Sulfonamides and Trimethoprim by LC-MS/MS (11010870)
- Tetracyclines by LC-MS/MS (11010091)
- Pesticides by GC and LC-MS (11011480)

EXAMPLE

APPENDIX III – SC-146E

 <p>UNITED STATES DEPARTMENT OF AGRICULTURE AGRICULTURAL MARKETING SERVICE</p> <p>CERTIFICATE OF QUALITY AND CONDITION (PROCESSED FOODS)</p>	<p>Please refer to this certificate by number and inspection office.</p>																				
	<p>A-000000</p>																				
<p>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 counterfeit 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.</p>	<p>DATE March 22, 2019</p>																				
<table border="1"> <tr> <th>APPLICANT</th> <th>ADDRESS</th> </tr> <tr> <td>ABC Honeymaker, Inc.</td> <td>Anytown, WI 12345</td> </tr> <tr> <th>RECEIVER OR BUYER</th> <th>ADDRESS</th> </tr> <tr> <td>Sarant</td> <td>HULL, UNITED KINGDOM</td> </tr> <tr> <th>SOURCE OF SAMPLES</th> <th>PRODUCT INSPECTED</th> </tr> <tr> <td>OFFICIALLY DRAWN</td> <td>FREE FLOWING DRIED HONEY POWDER</td> </tr> <tr> <th colspan="2">CODE MARKS ON CONTAINERS</th> </tr> <tr> <td colspan="2">dhp1234...</td> </tr> <tr> <th colspan="2">PRINCIPAL LABEL MARKS</th> </tr> <tr> <td colspan="2">"ABC DRIED HONEY"</td> </tr> </table>	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"		
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<p>CONDITION: Product was produced in an establishment which meets the requirements of the HACCP principles in accordance with "the relevant provisions of EU Regulations (EC) no. 852/2004."</p>																					
<p>Grade: Product meets "the relevant provisions of EU Regulations (EC) NO. 852/2004."</p>																					
<p>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 HACCP principles in accordance with "the relevant provisions of EU Regulations (EC) No. 852/2004."</p>																					
<p><i>Pursuant to regulations issued by the Secretary of Agriculture under the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621-1627), 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.</i></p>																					
<table border="1"> <tr> <th>ADDRESS OF INSPECTION OFFICE</th> <th>SIGNATURE OF INSPECTOR</th> </tr> <tr> <td>2490 Enterprise Drive, Oshkosh, WI 54904</td> <td>Kim Agrader <i>Kim Agrader</i></td> </tr> </table>	ADDRESS OF INSPECTION OFFICE	SIGNATURE OF INSPECTOR	2490 Enterprise Drive, Oshkosh, WI 54904	Kim Agrader <i>Kim Agrader</i>																	
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Part II: Certification		Page 2 of 2
II. Health Attestation	II.A. Certificate Reference Number <div style="text-align: center; color: red; font-weight: bold; font-size: 1.2em;">A-000000</div>	II.B.
II.1. Public Health Attestation I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) and certify that honey, royal jelly and other apiculture products described above were produced in accordance with those requirements, in particular that they:		
<ul style="list-style-type: none"> — <input checked="" type="checkbox"/> come from (an) establishment(s) implementing a program based on HACCP principles in accordance with Regulation (EC) No 853/2004 — <input checked="" type="checkbox"/> 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 853/2004 <p style="text-align: center;">and</p> <ul style="list-style-type: none"> — <input checked="" type="checkbox"/> the guarantees covering live animals and products thereof provided by the residue plans submitted in accordance with Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 86/368/EEC and 88/489/EEC and Decisions 89/187/EEC and 91/864/EEC (OJ L 126, 23.5.1996, p. 10), and in particular Article 29 thereof, are fulfilled. <p>Notes: Capital X means compliance.</p> <p>Part I</p> <ul style="list-style-type: none"> — Box reference 1.11: Place of origin: name and address of the dispatch establishment. Approval number means registration number. — Box reference 1.16: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in case of unloading and reloading. — Box reference 1.19: Use the appropriate Harmonised System (HS) code under the following headings: 04.09, 04.10. — Box reference 1.20: Indicate total gross weight and total net weight. — Box reference 1.23: Identification of container/Seal number: only where applicable. — Box reference 1.28: <i>Treatment type:</i> Indicate 'ultrasonication', 'homogenisation', 'ultrafiltration', 'pasteurisation', 'no thermal treatment'. <p style="text-align: center;"><i>Approval number of establishments:</i> approval number or competent authority identification number as appropriate</p> <p>Part II</p> <ul style="list-style-type: none"> — The color of the stamp and signature must be different to that of the other particulars of the certificate. 		
Official Inspector Name (in capitals): <u>KIM AGRADER</u> Qualification and Title: <u>Agricultural Commodity Grader</u> Signature: <u>Kim Agrader</u> Date: <u>February 15, 2019</u>		
<p><small>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.</small></p> <p><small>WARNING: Any person who knowingly falsely make, issue, alter, forge, or counterfeit 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 (7 U.S.C. 1622 (h)).</small></p> <p><small>The conduct of all services and the licensing of all personnel under the regulations governing such services shall be accomplished without discrimination as to race, color, religion, sex, or national origin.</small></p>		

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