**进口蜂蜜境外生产企业注册条件及对照检查要点**

**REGISTRATION CONDITIONS AND GENERAL PROVISIONS FOR CARRYING OUT OF CONTROL INSPECTIONS OF FOREIGN ESTABLISHMENT PRODUCING OF HONEY FOR IMPORT**

企业名称及注册编号 / **Name and approval number of establishment：**

企业地址：/ **Address of establishment:**

填表说明：/ **Mannual for completition the table**

1.根据《进口食品境外生产企业注册管理规定》（原国家质量监督检验检疫总局令第145号公布，根据海关总署令第243号修订），向中国申请注册的境外蜂蜜生产企业，其卫生条件应当符合中国法律法规和标准规范的有关规定，符合输华蜂蜜检验检疫议定书要求。本表供进口蜂蜜境外主管官方根据所列主要条件及依据，对照审查要点对蜂蜜生产企业开展官方检查；同时，境外蜂蜜生产企业根据所列主要条件及依据，填报并提交证明性材料，对照审查要点也可开展自我检查，用于企业申请注册前的自我评估。/

**According to "The administration of the registration standards of foreign producing establishments of imported foods" (published in the Order of the General Administration of Quality Supervision, Inspection and Quarantine of the People’s Republic of China (AQSIQ) No. 145 with amendments in accordance with the Order of the General Administration of Customs of the People's Republic of China (GACC) No.243), the sanitary conditions of the foreign honey-producing establishment applied for registration to the People’s Republic of China, must comply with the currently legislation and provisions of the standards of the People's Republic of China, as well as with the requirements of the Protocol of inspection and quarantine control of honey imported into the People's Republic of China. This form is intended for official foreign competent authorities as a list of general conditions, criteria and critical control points (CCP) for carrying out of the official inspections of honey-producing establishments for export of honey to the PRC. The foreign honey-producing establishments have to complete and provide documents in accordance with the general conditions and criteria, described here. In accordance with the general conditions regarding the control audits, an establishment can carry out self-audit and use them for self-assessment before providing the application for registration.**

2.境外主管官方及境外蜂蜜生产企业应根据对照检查的实际情况如实作出符合性判定。/

**Foreign official competent authority and the foreign honey-producing establishment have to form an opinion for conformity with the actual results of the such inspection.**

3.提交材料应用中文或英文填写，内容真实完整，附件应当进行编号，附件编号及内容应与“填报要求及证明材料”栏中的项目编号及内容准确对应，同时提交证明材料附件目录。/ **All documents should be completed in Chinese or English. The content of these documents should be complete and accurate. The annex must contain a reference number. The reference number and content of the annex must exactly match the number and content of the annex in the column "** **Filling-in Requirements and Supporting Information ". The confirmation documents should be provided with accompanying materials.**

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| 项目  **Item** | 主要条件及依据  **Sanitation Conditions/Legаl basis/** | 填报要求及证明材料  **Filling-in Requirements and Supporting Information** | 审查要点  **Key points of Review and Audit/** | 符合性判定  **Compliance**  **(Yes/No)/** | 备注  **Remarks** |
| **1、企业基本情况 / Basic Information of Establisment** | | | | | |
| 1.基本情况  **Basic information** | 1.《进口食品境外生产企业注册管理规定》第六条、第七条  **Articles 6 and 7 of the Administration of Registration of Foreign Food Establishments intended to be imported into the P.R.China**  2.《中华人民共和国食品安全法》中九十七条  **Law of the PRC «On Food Safety»( Article 97)** 3．申请国主管当局与海关总署签订的输华蜂蜜 检验检疫议定书 /**Protocol between the State Service of Ukraine on Food Safety and Consumer Protection and the General Administration of Customs of the People`s Republic of China on inspection, Quarantine Sanitary Requirements for Honey to be Exported from Ukraine to People`s Republic of China** | 1.填写《进口蜂蜜境外生产企业注册申请表》  **Fill in the form of Application For Export of Honey to P.R.China** | 1.企业应如实填报信息，基本信息应与出口国主管部门提交的信息一致、应与实际生产加工情况一致**Establishmets shall fill the true information in the application form, which shall be in line with the actual production of the establishment and the information provided by the competent authority**  2.人力资源（企业和官方）应能满足企业生产加工和官方检验监管的要求**Human resources (establishments and official veterinarians) shall be able to meet the needs of establishment production and official inspection control**  3.拟输华蜂蜜应符合议定书规定的产品范围**Honey to be exported to China must fall within the scope of products specified in the Protocol**  4.包装及标签要求符合双边议定书及国标要求/ **Packaging and labelling must comply with the requirements of the bilateral Protocol and national standards** | □符合**Yes**  □不符合**No** |  |
| **2．企业位置、车间布局和设施设备 /** **Location, Workshop Layout and Facilities & Equipments** | | | | | |
| 2.1企业所处地区环境 / The location and environment of establishment | 《食品安全国家标准 食品生产通用卫生规范》（GB 14881）中3 **/«National Food Safety Standard. General Hygiene Practice for Food Production»( GB 14881)(Article 3)** | 2.1提供厂区所处地区环境的图片，图片中应标明周围环境信息（市区、郊区、工业、农业和居民区）/ **Provide pictures of the establishment location and environment, indicating clearly the surrounding environment information (urban, suburban, industrial, agricultural, residential areas, etc.).** | 厂区周围不应有污染源 / **No pollution sources shall be found around the plant area.** | □符合 **Yes**  □不符合 **No** |  |
| 2.2企业布局 / **Location of the establishment** | 《食品安全国家标准 食品生产通用卫生规范》（GB 14881）中4.1 / **National Food Safety Standard. General Hygiene Practice for Food Production»( GB 14881)( paragraph 4.1)** | 2.2提供企业平面图（标示出不同的操作区域范围，并用彩色箭头分别标示出人流和物流，标明废弃物存放区域）/ **The establishments plan should be provided (showing different operating zones or zones of activity, as well as color arrows showing directions of people and cargo moving ; the plan indicates waste storage zones)** | 车间布局合理，人流物流避免交叉污染。/ **Rational placement of production workshops. Directions of people and cargo moving does not cause cross contamination**. | □符合 **Yes**  □不符合 **No** |  |
| 2.3生产设备 / **Production equipments** | 1.《食品安全国家标准 食品生产通用卫生规范》（GB 14881）中5.2 / **National Food Safety Standard. General Hygiene Practice for Food Production ( GB 14881) (paragraph 5.2)**  2.申请国主管当局与海关总署签订的输华蜂蜜检验检疫议定书 / /**Protocol between the State Service of Ukraine on Food Safety and Consumer Protection and the General Administration of Customs of the People`s Republic of China on inspection, Quarantine Sanitary Requirements for Honey to be Exported from Ukraine to People`s Republic of China** | 2.3.1提供主要加工设备清单，包括设计生产能力信息 / **Provide a list of major equipments and facilities**  2.3.2如包括加工/调制工艺，请提供加工、调制、浓缩处理相关设备说明及设备照片。/ **If the manufacturing process incorporates processing / preparation technologies, the additional explanations regarding the appropriate equipment used for processing, preparation and concentration, as well as photographs of that equipment should be provided.** | 1.企业应配备与生产能力相适应的生产设备 / **Establishment shall be equipped with equipments in line with its production capacity** | □符合 **Yes**  □不符合 **No** |  |
| **3. 加工用水的供给 / / Processing water supply** | | | | | |
| 3.1加工用水的水质控制 / **Quality control of water for processing** | 1.《食品安全国家标准 食品生产通用卫生规范》（GB 14881）第5.1.1、5.1.2 / **National Food Safety Standard. General Hygiene Practice for Food Production»( GB 14881)( paragraphs 5.1.1,5.1.2)**  2.《生活饮用水卫生标准》（GB 5749）/ **Standards for Drinking Water Quality (GB 5749)/** | 3.1如果是企业自有水源，请说明水质控制的相关措施并提供最近一次生产用水水质检测报告（如适用）/ **In the case that the water source is owned by the establishment, please describe the relevant measures for water quality control and provide the latest test report on the water used in production (if applicable)** | 加氯处理加氯量应符合《生活饮用水卫生标准》（GB 5749）要求；如果不加氯，企业应确保水质符合《生活饮用水卫生标准》（GB 5749）要求 / **Chlorine dosage for chlorination treatment must meet the requirements of Standards for Drinking Water Quality (GB 5749); in case of no chlorination treatment, the establishment must ensure that the water quality meets the requirements of Standards for Drinking Water Quality (GB 5749)** | □符合 **Yes**  □不符合 **No** |  |
| **4.原料来源 / Source of raw materials** | | | | | |
| 4.1蜂蜜原料来源 / **Origin of raw honey** | 1.《中华人民共和国食品安全法》中九十七条/ **Law of the People’s Republic of China «Food safety» (Article 97);**  2.申请国主管当局与海关总署签订的输华蜂蜜检验检疫议定书 / **Protocol between the State Service of Ukraine on Food Safety and Consumer Protection and the General Administration of Customs of the People`s Republic of China on inspection, Quarantine Sanitary Requirements for Honey to be Exported from Ukraine to People`s Republic of China** | 4.1.1提供原料来自的 蜂场名单 / **Provide the list of apiaries, from which the raw material originate**  4.1.2来自第三国的蜂蜜原料，提供来源于原产国官方批准注册的 蜂蜜企业或蜂场名单（如适用） / **For raw honey originating from third countries, should be provided the list of establishment or apiaries approved and registered by the competent authorities of the countries (if applicable).** | 输华蜂蜜产品的原料来源或蜂场应经所在地官方主管部门批准并有效监管，符合双边议定书相关要求。 / / **The source of raw honey or apiary origin from where the products are imported into the People’s Republic of China, must have the necessary permissions provided by the local competent authorities and under permanent control and comply with the requirements of the bilateral Protocol** | □符合 **Yes**  □不符合 **No** |  |
| 4.2 原料验收 / **Receiving of raw materials** | 《食品安全国家标准 食品生产通用卫生规范》（GB 14881）中7.1、7.2 / **National Food Safety Standard. General Hygiene Practice for Food Production (GB 14881) (paragraphs 7.1,7.2)** | 4.2.1企业对原料供应方（例如养蜂场等）的要求及审核制度 / **Requirements of the establishment to the suppliers of raw materials (eg. apiaries) and how they are inspected.**  4.2.2提供原料验收制度（包括指标、限量、验收要求等，包括如何防止有毒有害蜜源进入工厂） / **Provide the description of the raw material receiving procedure (including indicators, restrictions, receiving requirements, as well as standards for preventing the flow of toxic or harmful raw honey to the production process).**  4.2.4如摇蜜环节不在本企业完成，请提供摇蜜企业的注册号码 / If the process of honey pumping is not **carried out at the establishment, should be provided the approval number of theother astablishment performing the process of honey pumping** | 蜂蜜生产过程中原料验收为关键环节，生产加工中使用原料应符合卫生规定要求。 / **Receiving of raw materials is a key element of the honey production process. Raw materials used during production and processing must comply with the established sanitary standards.** | □符合 **Yes**  □不符合 **No** |  |
| **5.加工过程控制 / Processing control** | | | | | |
| 5.1 加工过程关键工序及其控制情况 / **The main technological processing operations and their control.** | 1.《食品安全国家标准 食品生产通用卫生规范》（GB 14881）中8 / **National Food Safety Standard. General Hygiene Practice for Food Production ( GB 14881)( Article 8)**  2.申请国主管当局与海关总署签订的输华蜂蜜检验检疫议定书中规定的热处理要求 / **Heat treatment in accordance with requirements of the Protocol between the State Service of Ukraine on Food Safety and Consumer Protection and the General Administration of Customs of the People`s Republic of China on inspection, Quarantine Sanitary Requirements for Honey to be Exported from Ukraine to People`s Republic of China** | 5.1.1提供产品加工工艺流程图（如企业同时生产天然蜂蜜和浓缩加工/调制蜜，请分别描述生产工艺并提供相关生产技术参数，如过滤网目数，浓缩加热温度、时间及压力，添加物质等）/ **Provide the production flow chart (if the establishment carries out simultaneous production of natural honey and concentrated processed/ prepared honey: provide the separate descriptions of production processes, as well as relevant technical parameters of production, eg the number of borders for strainers, heating temperature, duration and pressure regime for the process of concentration , supplements, etc.)**  5.1.2提供危害分析工作单和HACCP计划表（如没有，请提供相应预防控制措施）。/ **Provide the hazard analysis worksheet and HACCP plan( if not, please provide corresponding preventive control measures).** | 1.生产工艺流程应合理 / **The technological production process must be rationally organized.**  2.对影响蜂蜜安全卫生的关键工序，应制定明确的操作规程，保证控制有效、及时纠正偏差、持续改进不足，做好记录 / **For the main technological operations that affect the safety and hygiene of honey, the clear rules of implementation must be developed to ensure control efficiency, timely elimination of deviations, and continuous improvement of deficiencies.** | □符合 **Yes**  □不符合 **No** |  |
| 5.2自检自控 / **Self- audit and control** | 1.《食品安全国家标准 食品生产通用卫生规范》（ GB 14881）中9 / **National Food Safety Standard. General Hygiene Practice for Food Production( GB 14881) (Article 9)** | 5.2.1企业有自属实验室，提交企业实验室能力与资质证明；企业委托第三方委托实验室，提供委托实验室资质 / **In case of laboratory owned by the establishment, submit certificates for its laboratory capability and qualification; in case of laboratory entrusted by a third party, provide the qualification of the laboratory entrusted**/  5.2.2提供企业监控计划，包括监控项目、频率、判定标准、不合格处理措施等 / **Provide the monitoring plan made by establishments which shall shall specify the monitoring items, frequency, limit criteria and follow-up action of non-conformity etc** | 企业应建立自检自控计划，原料和产品检测的采样、检测和判定标准应符合中国要求，确保产品安全卫生。/ **The establishment shall establish a self-audit and control plan. The sampling, testing and limit criteria for raw materials and final products shall meet the requirements of competent authorities and China to ensure the safety and wholesome of products** | □符合 **Yes**  □不符合 **No** |  |
| **6.食品添加剂和包装材料管理 / Management of** **food additives and packaging materials** | | | | | |
| 6.1食品添加剂控制 / **Control of food additives** | 1.《食品安全国家标准 食品生产通用卫生规范》（GB 14881）中7.3 / **National Food Safety Standard. General Hygiene Practice for Food Production»( GB 14881) (paragraph 7.3)**  2.《食品安全国家标准 食品添加剂使用标准》（GB2760） / **National Food Safety Standard. Chinese Standards for Food Additives (GB2760)** | 6.1提供食品添加剂使用清单及使用量（适用时）/ **Provide the list of the food additives used, indicating their quantity (if applicable).** | 企业应建立食品添加剂控制程序，食品添加剂使用应符合中国GB2760要求 / **The establishment is required to develop the food additives control program. Using of food additives must comply with GB2760.** | □符合 **Yes**  □不符合 **No** |  |
| 6.2 内外包装材料管理贮存 / **Management and storage of exterior and interior packing materials** | 1.《食品容器、包装材料用添加剂使用卫生标准》（GB9685）/ **National Food Safety Standard: Standard for the Use of Additives in Food Contact Materials and Articles (GB9685).** 2.申请国主管当局与海关总署签订的输华蜂蜜检验检疫议定书中规定的包装要求 / **Requirements for packaging in accordance with the Protocol between the State Service of Ukraine on Food Safety and Consumer Protection and the General Administration of Customs of the People`s Republic of China on inspection, Quarantine Sanitary Requirements for Honey to be Exported from Ukraine to People`s Republic of China** | 6.2提供包装材料清单和内外包装材料适合进行蜂蜜包装的证明材料 / **Provide the list of packing materials and supporting materials indicating the internal and external packing materials are suitable for packing honey** | 向中国出口的蜂蜜产品必须用符合中国食品安全国家标准和国际卫生标准的全新材料包装。/ **The new packaging materials used for honey products exported to the People’s Republic of China, meet national food safety standards of the People’s Republic of China and international hygiene standards** | □符合 **Yes**  □不符合 **No** |  |
| **7.人员管理及培训 / Personnel Management and Training** | | | | | |
| 7.1 员工资格和健康情况 / **Staff qualification and health management** | 1.《中华人民共和国食品安全法》第四十五条 / **Law of the People’s Republic of China «Food Safety» (Article 45)**  2.《食品安全国家标准 食品生产通用卫生规范》（ GB 14881）中6.3.1 / **National Food Safety Standard. General Hygiene Practice for Food Production»( GB 14881)(paragraph 6.3.1)** | 7.1提供员工雇佣前健康管理以及员工体检要求 / **Provide pre-employment health management and medical examination requirements for employees** | 雇用前员工应进行体检并证明适合在食品加工企业工作；  员工应定期体检并保存记录 / **The employees must be medically examined and certified to be fit for the work in food processing establishments prior to employment** | □符合 **Yes**  □不符合 **No** |  |
| 7.2人员培训 / **Personnel training** | 《食品安全国家标准 食品生产通用卫生规范》（ GB 14881）中12 / **National Food Safety Standard. General Hygiene Practice for Food Production ( GB 14881)(Article 12)** | 7.2提供员工年度培训计划、内容、考核、记录 / **Provide employee annual training plan, including training content, assessment and records** | 培训内容应涵盖输华蜂蜜检验检疫议定书、中国法规标准等内容。/ **The training content shall cover the Protocol between the State Service of Ukraine on Food Safety and Consumer Protection and the General Administration of Customs of the People`s Republic of China on inspection, Quarantine Sanitary Requirements for Honey to be Exported from Ukraine to People`s Republic of China** | □符合 **Yes**  □不符合 **No** |  |
| **8. 产品追溯和召回 / Product Traceability and Recal** | | | | | |
| 8.1产品追溯和召回体系 / **Product traceability and recall system** | 1.《中华人民共和国食品安全法》 第四十二条 / **Law of the People’s Republic of China «Food Safety» (Article 42)** 2.申请国主管当局与海关总署签订的输华蜂蜜检验检疫议定书中规定的追溯和召回要求 / **Requirements for product traceability and recall system in accordance with the Protocol between the State Service of Ukraine on Food Safety and Consumer Protection and the General Administration of Customs of the People`s Republic of China on inspection, Quarantine Sanitary Requirements for Honey to be Exported from Ukraine to People`s Republic of China** | 8.1简述产品追溯程序，以一批次成品批号为例，说明如何自成品追溯至相应蜂场 / **Briefly describe the product traceability procedure, and take the batch number of a finished products as an example to explain how to trace the finished products to the farm or establishment where the raw material come from** | 建立并有效执行产品追溯系统，准确记录并保持食品链相关食品安全信息和批次、标识信息。输华蜂蜜产品须在加工过程和成品包装上对来自不同蜂场的蜂蜜原料进行有效识别。/ **Development and effective implementation of traceability product systems, accurate recording and storage of food safety information, batch numbers and labeling within the food production chain. During processing and packaging of finished products exported to the People’s Republic of China, honey from different apiaries must be properly labeled for identification purposes.** | □符合**Yes**  □不符合 **No** |  |
| **9.声明 / Declaration** | | | | | |
| 9.1 企业声明 / **Declared by establishment** |  | 1.填写《进口蜂蜜境外生产企业注册申请表》/ **Application form for the registration of a foreign manufacturing establishment for export of apiculture products (honey) should be completed** | 应有法人签名和公司盖章 / **The form shall be signed by responsible person and stamped with seal of the establishment** | □符合 **Yes**  □不符合 **No** |  |
| 9.2兽医主管当局确认 / **Confirmed by Competent Authority** |  | 1.填写《进口蜂蜜境外生产企业注册申请表》 / **Application form for the registration of a foreign manufacturing establishment for export of apiculture products (honey) should be completed** | 应有主管兽医签名和主管当局盖章 / **The form shall be signed by official veterinarian in charge and stamped with official seal of the Competent Authority** | □符合 **Yes**  □不符合 **No** |  |