



衛生福利部
食品藥物管理署
Taiwan Food and Drug Administration

**QUESTIONNAIRE FOR EQUIVALENCE EVALUATION OF THE
SAFETY CONTROL SYSTEM OF ANTLER/VELVET OF CERVIDS**

鹿角產品安全管理體系等效性評估問卷

2022.08

Note for competent authority before filling out this questionnaire

主管機關填寫本問卷前之提醒事項

- In this questionnaire, Antler/velvet of cervids is equivalent to “products of Cervidae origin” that are listed in HS codes under headings 0507 with import regulation F01 or F02, originated from states or zones where chronic wasted disease (CWD) occurred.
本問卷所提「鹿角」等同於「來自曾發生鹿慢性消耗病(CWD)國家、貨品分類號列 0507 項下且具 F01 或 F02 輸入規定之『其他鹿來源產品』」。
- The requested information should be provided in English or Mandarin (Chinese).
所要求之資訊應以中文或英文提供。
- Legal citations and related documents corresponding to each question should be as complete as possible. Electronic files of those documents should be provided. Not only the list of laws/regulations/documents but concise and clear description should be summarized to satisfy as each question requests.
應盡可能完整提供本問卷中要求的法源依據及相關文件，並提供電子檔。除法規/文件外，尚應就各問項要求，簡短且清楚地摘要描述其重點。

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1. GENERAL INFORMATION

一般資訊

1.1. Please provide the official name of your country.

請提供貴國之官方國名

1.2. Please provide the abbreviations and explanations used in this questionnaire (Table 0).

請提供填寫本問卷時所使用之縮寫及其釋義。



Table 0.docx

1.3. Please introduce the industry of Antler/velvet of cervids in your country, and please provide the statistics of importation and exportation of Antler/velvet of cervids over the past two years (Table 1-1 and 1-2)

請簡介貴國鹿角相關產業概況，並依表單 Table 1-1 及 Table 1-2 提供過去 2 年鹿角產品進出口相關統計資料。



Table 1.docx

1.4. Please provide information of the Antler/velvet of cervids that seek market access to Taiwan (Table 2).

請於表單 Table 2 提供欲申請輸入臺灣之鹿角產品資訊。



Table 2.docx

2. LAWS & REGULATIONS

法令規章

Please describe the frameworks/hierarchical relationship among the laws and regulations concerning food safety of Antler/velvet of cervids.

請說明鹿角與食品安全有關法規之架構及層級關係。

3. COMPETENT AUTHORITIES

主管機關

- 3.1 Please provide information listed in Table 3, including the name, role and responsibilities, and legal reference, of the competent authorities (central, regional and local) in charge of each area for Antler/velvet of cervids .

請依表單 Table 3，填具負責鹿角管理之中央、區域、地方之主管機關之名稱、角色與權責及法源依據。



Table 3.docx

- 3.2 Please provide organizational charts of every competent authority mentioned in Table 3.

請提供 Table 3 所提及各個主管機關之組織圖。

- 3.3 Please describe the mechanisms of coordination, cooperation and reporting of cases among each competent authority mentioned in Table 3 concerning food safety control on Antler/velvet of cervids .

請說明 Table 3 所提及各個主管機關之間，在鹿角食品安全管理之協調合作及案件通報機制。

- 3.4 Please provide the number of officials and other authorized personnel of each competent authority responsible for Antler/velvet of cervids at central, regional, and local levels as listed in Table 4.

請於表單 Table 4 提供鹿角管理相關之個別主管機關中央、區域和地方各部會權責人員的人數。



Table 4.docx

- 3.5 Please describe the recruitment procedures, required qualifications details or(and) years of working experience, and training requirements for officials and other authorized personnel for each following area of competence in offices/functions at central, regional, and local levels, respectively:

- A. Food safety and sanitary policy
- B. Establishment inspection
- C. Laboratory services for CWD

D. Export control (including certification and inspection)

E. Import control

請依食品安全衛生管理、生產設施查核、實驗室檢測、出口管制(含發證及查核)及進口管制等權責，說明中央、區域和地方各級辦公室/部門的官員和其他授權人員的招聘程序、資歷或(與)工作年資要求及訓練要求。

4. FOOD SAFETY MANagements AND CONTROL SYSTEMS

食品安全管理及管控體系

4.1. Please provide comprehensive flowcharts to demonstrate the production of Antler/velvet of cervids in your country from cervid animals to the products; following information along with photos or schematic diagram shall be included:

- A. Antler/velvet-harvesting condition; e.g. animal sources, age of the animals, season, antler parts that are harvested (upper/middle/lower etc.), whether cartilaginous tissues and blood vessels remain in the core of antler/velvet or completely calcified, etc.;
- B. Each step from green antler/velvets to products;
- C. Any processing techniques that are used and their operating conditions; e.g. dipping, heating, drying, vaporizing, freezing, slicing, etc.;
- D. Specification requirement (in related to food safety or sanitation) of each product form of Antler/velvet of cervids.

請提供完整流程圖以呈現貴國從鹿動物至產品之鹿角生產過程，並應包括下列事項及其照片或示意圖：

- A. 鹿角採收條件，例如動物來源、動物年齡、季節、採收部位(上/中/下部)、鹿角中心含軟骨組織及血管或已完全鈣化等；
- B. 自生鹿角至產品之各個步驟；
- C. 任何使用到的加工技術及其操作條件，例如：浸泡、加熱、乾燥、燻蒸、冷卻、切片等。
- D. 各形態鹿角產品之(食品安全衛生相關)規格要求。

4.2. Please describe the management of veterinary drugs related to Antler/velvet of cervids, including:

- A. Competent authorities, procedure of evaluation and approval, legal references, control on the use of veterinary drugs, and the list of veterinary drugs permitted for the therapeutic and preventative use in Cervid animals;
- B. Competent authorities, procedure and legal references of setting maximum residue limit (MRL), and a list demonstrating the limit of quantitation (LOQ) and(or) MRLs of prohibited and approved veterinary drugs in foods;

請說明鹿角相關之動物用藥管理，包括：

- A. 動物用藥之使用(主管機關、評估及核准程序、法源、管控、准用於鹿動物之治療性與預防性動物用藥清單)；
- B. MRL 制定(主管機關、制定程序、法源、准用與禁用動物用藥之 LOQ 與(或)MRL 清單)；

4.3. Please describe the management of substances that are used to disinfect or apply to harvested antlers/velvets; including competent authorities, legal references, and evaluation and approval procedures, and list of permitted substances with their restriction.

請說明用於消毒或施於採收鹿角之物質之管理，包括主管機關、法源、評估和核准程序及核准物質清單及其限制。

4.4. Please describe the procedures and management for the granting, suspension, and withdrawal of registration of establishments of Antler/velvet of cervids , including competent authorities, relevant requirements, legal references and guidance documents.

請描述鹿角生產設施登記之核准、暫停和撤銷程序及管理，包括主管機關、相關條件要求、法源及指引文件。

4.5. Please provide a map of your country showing the locations of establishments regarding production of Antler/velvet of cervids .

請提供貴國家地圖指出鹿角之生產設施的位置。

4.6. Please provide information in Table 5 for each species of cervids from individual establishments that are approved to export Antler/velvet of cervids .

請於表單 Table 5 依各個鹿之物種，提供核准出口鹿角生產設施之資訊。



Table 5.docx

4.7. Please describe the laws/regulations in your country related to requirements on hygiene management and “self-check” control for the operators (files of the legislation shall be provided), and please describe how does government verify the effectiveness of the management.

請詳述貴國鹿角生產衛生管理及要求業者執行自我檢查管控之法規(併提供檔案)及其內容，並請說明政府如何確認生產業者執行管控之有效性。

4.8. Please indicate the requirements that operators are required to notify the competent authority or official services with CWD cases; legal reference and epidemiological reports for each case of CWD in your country shall be provided.

請指出生產業者針對 CWD 案件應通報主管機關或相關單位之要求，並提供其法源及在貴國所發生各起 CWD 案件之流行病學報告資料。

4.9. Please describe the surveillance plan and cervid identification/traceability system for the prevention of CWD.

請描述為防範 CWD 所實施之監控計畫及鹿隻鑑別/追溯追蹤系統。

4.10. Please describe the implementation of hygiene and infectious material (e.g. saliva, urine and feces of CWD-infected animals) removal measures for the prevention of CWD contamination.

請描述為防範 CWD 污染所實施衛生及去除感染性物質(例如感染 CWD 動物之唾液、尿液及糞便)之措施。

5. OFFICIAL CONTROLS

官方管制

5.1. Please describe how the competent authorities organize inspections on establishments for Antler/velvet of cervids; following information shall be included:

- A. Type, theme, frequency, instructions, and checklists used for tasks related to inspections concerning food safety and sanitation, processing process, traceability and relevant issues;
- B. Principles that determine inspection frequency by risk ranking;
- C. Procedures of inspection and their verification mechanism;
- D. Result-reporting mechanism of inspections.
- E. Copy of annual official control program in the previous year and the year before last year.

請說明主管機關與相關單位如何規劃執行鹿角生產設施之查驗，提供資訊應包含：

- A. 與食品安全衛生、生產過程、追溯追蹤等相關領域之查驗類型、主題、頻率、指引及查檢表；
- B. 依據風險高低分類決定查驗頻率之原則；
- C. 查驗程序及其確效機制；
- D. 查驗結果通報機制；
- E. 近二年之年度查驗計畫。

5.2. Please fill out Table 6 for information of official controls on OPERATORS of Antler/velvet of cervids .

請依 Table 6 填列對鹿角相關業者之官方管制資訊。



Table 6.docx

5.3. Please fill out Table 7 for information of official SAMPLING and TESTING of Antler/velvet of cervids during official control.

請依 Table 7 填列官方管制中對鹿角之官方抽樣檢驗資訊。



Table 7.docx

5.4. Please describe the inspections/controls carried out by non-government (private) entities (if exist), including name of the entities, enforcement frequencies, delegated tasks and how the competent authority oversees their inspection/control activities.

請說明由非政府(私部門)單位執行之查驗/管制內容(如有)，包括該相關單位之名稱、執行頻率、主管機關如何監督這些單位的查驗/管制活動。

5.5. Please describe the procedures of actions to be taken and legal references of administrative execution (e.g. investigation, suspension, confiscation, destroy, recall, withdrawal, fines and penalties, prosecution and judicial adjudication, etc.) for EACH following scenario:

A. Specific operator is reported with suspicion of non-compliance;

B. Unsatisfactory results of official controls, including those on activities of operators, on product sampling and testing and examination on false labeling;

C. Operator fails to correct non-compliances.

請說明下列各項情境因應措施之行政程序(如調查、暫停措施、沒入、銷毀、下架、回收、罰款與罰則、起訴與司法審判等)及其法源：

A. 特定業者遭檢舉疑似有不符合規定情形；

B. 官方管制(包括對業者之行為、對產品之抽樣檢驗及對標示錯誤之檢查)有不符合要求之結果；

C. 業者未能改正其不符合規定情形。

5.6. Please describe the mechanism reacting to food safety emergencies relevant to Antler/velvet of cervids ; legal reference shall be included.

請說明當鹿角相關之食品安全事件發生時之反應機制及其法源依據。

6. LABORATORY

實驗室

6.1. Please describe the diagnostic approach for CWD in detail; relevant documents shall be provided.

請詳述針對 CWD 之診斷方法，並提供相應文件。

6.2. Please describe the prerequisites and legal reference for laboratories to be designated by the competent authority to perform CWD official testing; following information shall be included:

- A. Accreditation and quality management systems such as good laboratory practice (GLP), ISO, etc.;
- B. Allocation (number) and training requirements of personnel for CWD testing;
- C. Record keeping system for the analytical results.

請說明實驗室得供主管機關指定為執行 CWD 官方檢測之前提要求及法源依據，其中應提及：

- A. 認證及品質管理體系如 GLP 或 ISO 等；
- B. 執行 CWD 檢測人員之配置及訓練要求；
- C. 分析結果之紀錄保存系統。

6.3. Please fill out Table 8 for EACH individual laboratory designated by the competent authority to carry out official testing (including CWD and veterinary drugs, etc.) on Antler/velvet of cervids .

請依表單 Table 8 提供執行主管機關所指定執行鹿角官方檢測(包括 CWD 及動物用藥等)之各個實驗室之資訊。



Table 8.docx

7. IMPORT CONTROLS

輸入管控

7.1. Please describe the mechanisms of your country to evaluates a country's food safety system as equivalent and eligible to export Antler/velvet of cervids to your country.

請說明貴國評估一個國家的食品安全體系是否具等效性且可輸入鹿角至貴國之機制。

7.2. Please list the countries that have market access for their Antler/velvet of cervids to import to your country; if there are restriction, preference or requirements, they shall also be indicated.

請列出貴國准許輸入鹿角之國家；倘有限制、優惠或要求，則應予註記。

7.3. Please describe the import controls on Antler/velvet of cervids ; following information with legal reference shall be provided:

- A. Procedures of custom clearance regarding food safety requirements at import, including eligibility check, sanitation requirement and issuance of import permits;
- B. Certificates on food safety and sanitation; including the mechanisms to check and verify authenticity of the certificates;
- C. Sampling and testing at import inspection;
- D. Procedures for controls on products transiting the country.

請說明輸入鹿角管控制度，應包括下列事項及其法源：

- A. 涉及食品安全要求之輸入通關程序，包括資格檢查、衛生要求及輸入許可之核發；
- B. 食品安全衛生證明，包括檢查及核認真實性之機制；
- C. 輸入查驗階段之抽驗；
- D. 對於中轉產品之管控流程。

8. EXPORT CONTROLS AND CERTIFICATION

出口管控及證書

8.1. Please describe internal and(or) external audit system (if exist) for ensuring that Taiwan requirements are satisfied by export-approved establishments.

請說明確認出口生產設施符合臺灣規範之內部及(或)外部稽核系統(如有)。

8.2. Please describe the procedures for issuing certificates for exporting dispatched from approved establishments; following information shall be included:

- A. Any digital management systems involved;
- B. Registration/licensing requirements for export;
- C. By what means do exporters submit application to whom with what documents;
- D. Examination and reviews done by competent authorities or official services (central, regional, or local levels shall be indicated)
- E. How do the certifying officers certify the information on certificates, including

- whether all food safety and sanitary requirements are met;
- F. Procedures following identifying non-compliances; including corrective actions and follow-up;
- G. Verification of consignment before/during loading
- H. Signing and issuance.

請說明就核准生產設施出貨輸出之核發證明文件程序，包含下列資訊：

- A. 任何相關的數位管理系統；
- B. 輸出業者之登記/註冊規範；
- C. 輸出者透過何種方式、檢具何種文件、向誰提出申請；
- D. 主管機關或官方單位(應註明為中央、區域或地方)執行的檢查及審查；
- E. 核證人員如何確認證明文件上的資訊，包括是否已符合所有食品安全衛生之要求；
- F. 當發現不符合情形時之流程，包括矯正行動及後續追蹤；
- G. 裝貨前(時)之貨物確認；
- H. 簽章及核發。

8.3. Please describe the control systems for issuing certificates; following information shall be included:

- A. Authorization, required qualifications, competencies, and training of certifying officers;
- B. The systems/mechanisms to link the certificate to the consignment and to the certifying officer;
- C. The mechanisms to prevent false or misleading certification; including penalties, and how the authenticity of certificates are guaranteed.

請說明核發證明文件之管控系統，包含下列資訊：

- A. 核證人員之授權、所需資格、能力及訓練資訊；
- B. 系統或機制以達到證書、貨物及核證人員相連結；
- C. 預防偽造或不實發證之機制，包括罰則及如何確保證書之真實性。

8.4. Please list the countries that open their market access for your country to export Antler/velvet of cervids to; if there are restriction, preference or requirements, they shall also be indicated.

請列出開放貴國輸出鹿角之國家；倘有限制、優惠或要求，則應予註記。

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