

3. DRAFT ANNEX TO CXG 89-2016 – PRINCIPLES AND GUIDELINES TO HARMONISE THE USE, DESIGN, IMPLEMENTATION AND UPDATE OF ESTABLISHMENT LISTS

Section 1 - Preamble

1. Establishment list(s) and establishment listing refers to information exchange between importing and exporting countries on eligibility of individual Food Business Operators (FBOs) to trade specific food products or groups of food products.
2. Most trade in foods occurs without the need for establishment lists to be developed or maintained by importing and/or exporting countries. However, should an importing country consider developing or maintaining establishment lists, this annex should be used in accordance with the principles and guidelines on information exchange laid out in CXG 89-2016.
3. Establishment lists are mentioned in several CCFICS documents¹. In international trade, establishment lists can be used to identify establishments in the exporting country that are eligible to export specific food products or groups of products to the importing country, and that a National Food Control System (NFCS)² is in place which oversees Food Business Operators (FBOs) seeking to export food. Establishment lists, however, should not be considered a necessary component of an import/export protocol.
4. Use of this annex should decrease the requirements for burdensome information-collection, whilst ensuring that, if necessary to address a specific, identified food safety risk, essential information is readily available to importing countries Competent Authorities (CAs).

Section 2 – Purpose and objective

5. The purpose of this annex is to provide further principles and guidelines to CAs when determining whether the use of establishment lists may be justified, and when justified, how this can be operationalized in an appropriate, cooperative and least trade restrictive manner. Use of this annex will facilitate harmonized, streamlined and timely information sharing.
6. This annex is not intended to encourage the use of establishment lists by importing countries CAs and should not result in increased or duplicative requirements for such lists.
7. The objective of this annex is to minimize the burden of establishment listing while protecting the health of consumers and ensuring fair practices in the food trade, by promoting:
 - a. consistent, transparent, risk-based and system-based approaches to the initial considerations, use, design, implementation and update of establishment lists,
 - b. simplification and harmonization of information requirements and interoperable data formats, to facilitate efficient and reliable information exchange.

Section 3 - Scope

8. This annex applies to situations where the CAs of importing countries consider introducing or already have requirements for establishment lists from exporting countries. It sets out high level principles and guidelines for the consideration, design, implementation and update of such requirements. This annex also outlines the responsibilities of importing and exporting countries with regard to establishment listing.

Section 4 - Roles and Responsibilities

9. The following overarching roles and responsibilities, applicable to both importing and exporting country CAs when considering use, design, implementation and update of establishment lists, complement the more detailed principles, procedures and recommendations set out in sections 5-10 of this annex and should be read in conjunction with the relevant principles and guidance contained in CXG 89-2016 and related Codex texts. Importing and Exporting Country CAs should:
 - a. Cooperate in a transparent, reliable, timely and efficient manner to protect the health of consumers and ensure fair practices in the food trade,
 - b. Apply a risk-based, proportionate and least trade-restrictive approach when considering the use, design, implementation and update of establishment lists,
 - c. Rely on and support a system-based approach, recognising the role of the exporting country's NFCS, rather than focusing on individual establishment assessments,

¹ CXG 26-1997, CXG 34-1999, CXG 38-2001, CXG 47-2003, CXG 89-2016

² CXG 82-2013 *Principles and guidelines for national food control systems (NFCS)*

- d. Minimise administrative burden by avoiding duplication, repetitive information requests and unnecessary data exchanges,
- e. Ensure that information exchange related to establishment listing does not disrupt trade, and
- f. Promote consistency, harmonisation and predictability in establishment listing processes.

Suggested new paragraph on FBOs roles and responsibilities:

[Where requested and in accordance with applicable regulatory requirements and procedures, FBOs are responsible for providing accurate, complete, and validated information relevant to establishment listing.]

Section 5 – Initial considerations

10. Before introducing, designing, implementing or updating requirements for establishment lists, the importing country CA should consider the principles and guidelines listed in paragraph 1 in the main document (CXG 89-2016). *Guidelines for Food Import Control Systems* (CXG 47-2003) contains the framework for the development and operation of an import control system and *Principles for Food Import and Export Inspection and Certification* (CXG 20-1995) contains pertinent information regarding certification, inspection, requirements, and risk assessment. In addition, the following Codex guidelines should be considered:
 - a. *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CXG 26-1997),
 - b. *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* (CXG 38-2001), and
 - c. *Guidelines on Recognition and Maintenance of Equivalence of National Food Control Systems (NFCS)* (CXG 101-2023).
11. Furthermore, the importing country CA should specifically consider whether:
 - a. establishment listing is necessary and proportionate when considering the food safety risks posed by specific food product or groups of products,
 - b. food safety objectives are met by existing experience, knowledge and confidence in the exporting country's NFCS, and/ or
 - c. food safety objectives can be or are met by mechanisms, other than establishment listing, which are less trade-restrictive and more efficient.

Section 6 – Principles

12. In addition to the principles listed in CXG 89-2016 Section 5 (bullet a – f), CAs should be guided by the following principles when considering whether to require establishment lists:
 - a. The administrative burden for both importing and exporting country CAs should be minimized. CAs should strive for efficiency in communication and avoid multiple exchanges of the same information and repetitive submissions. Re-use of previously provided information should be facilitated.
 - b. The use of establishment lists should be [based on evidence of risk] [based on risk] and should only be required where it is deemed necessary and proportionate to achieve public health objectives.
 - c. The level of information exchange and detail required by the importing country CA should be narrowly tailored to the risk posed by the specific food products or groups of products. Unnecessary and burdensome requests for detailed information which are not [based on evidence of risk] [based on risk], should be avoided.
 - d. Establishment listing should be grounded in a system-based approach rather than an individual establishment evaluation approach and should not be a first choice for importing country CAs to receive assurances about exporting country establishments or NFCS, which can be achieved by means other than establishment listing.
 - e. The requirement for establishment lists should be limited to the FBO conducting final manufacturing of the food products or groups of products exported and should not extend to other establishments along the food production chain, unless justified [based on evidence of risk] [based on risk] and specified by the regulatory requirements of the importing country CA.
 - f. The importing country CA should clearly define and share its relevant regulatory requirements. General references to the national legislation without specifying the requirements should be avoided.

- g. Establishment lists should not link eligibility of exporting country establishments to individual importers in the importing country. Separate listing processes per importer should be avoided.

Section 7 –Exchange of information (Process)

13. When the importing country CA's requirements for establishment lists have been justified based on risks posed by the specific food product or group of products to food safety, the importing and exporting countries CAs should follow the process as described in Section 6 in CXG 89-2016 for information exchange. In addition, the importing country CA should:
 - a. Provide a clear explanation and justification of the requirements, including through notification and consultation with exporting countries,
 - b. Share all pertinent information, including definitions, processes, requirements and clarifying terms with exporting country CAs, and allow an adequate transition period prior to their implementation to ensure that the requirements do not disrupt trade,
 - c. Consider, referencing to an updated lists of eligible establishments maintained by the exporting countries CAs on a publicly available official website or platform, where available, as an alternative to requiring a separate establishment list. Otherwise, the importing country CA should explain why the establishment list published by the exporting country CA does not meet their needs,
 - d. Upon request, clearly explain to the exporting country CA the [evidence of risk] [risk basis] for requiring establishment lists,
 - e. Consider allowing exporting countries CAs to provide information by other means, to demonstrate that they are managing the risk to an acceptable level, instead of implementing requirements for establishment lists,
 - f. Avoid requesting more than one establishment list for the same products or groups of products, when there are multiple CAs in the importing country, to prevent unnecessary burdens on CAs and FBOs in the exporting countries,
 - g. Acknowledge that if the NFCS of the exporting country is recognised by the importing country CA, and the exporting country has submitted a list of eligible establishments, the importing country should publish the received list and allow imports to commence without undue delay.

Suggested new paragraph:

[Importing country Competent Authorities (CAs) may also consider allowing FBOs to register or submit establishment listing information through digital platforms (such as Single Window systems or equivalent interoperable solutions), to facilitate efficient, secure and streamlined information exchange.]

Section 8 – Format, use and implementation

14. Information requirements for establishment list processes should recognize, and not duplicate controls, inspection and approval processes already imparted by the NFCS of the exporting country.
15. The information required for the list should be limited to what is necessary to identify eligible establishments. This should be limited to information readily available in CA's NFCS. Information that may be provided in the establishment list includes:
 - a. Name of establishment
 - b. Approval/registration number of the establishment in exporting country
 - c. Address
 - d. Activities for which the establishment is approved by the exporting country CA
 - e. Product category, as appropriate, for which the establishment is approved by the exporting country CA.
16. If additional information beyond what is listed in paragraph 15 (a – e) is required, the importing country CA should explain why this information is necessary, with reference to the [evidence of risk] [risk basis].
17. Any additional information should be used only for the purposes for which it was collected and should be protected from inappropriate use or disclosure to other parties.
18. Commercially sensitive and personal data should not be required as part of establishment listing.
19. The importing country CA should provide and clearly explain the format of the list and the information required. Recognising that certain information elements (for example address) may be structured

differently in different countries the importing country CA should, where possible, allow the same format as is used in the systems of the exporting country.

20. The importing country CA should accept electronic exchange of establishment lists, and paper copies should be avoided. The use of internationally recognized data standards is encouraged to ensure harmonized data fields and facilitate interoperability.
21. The importing country CA should make the establishment lists publicly available online in a timely and transparent manner, ensuring accessibility to the exporting country.

Section 9 - Updating and amendments

22. The importing country CA should:
 - a. Have in place an efficient system and clear procedures which allows transparent, accurate and timely updating and publishing of the list and which does not require duplication of processes or repeating submission of information already provided,
 - b. Ensure that errors on the list are amended without undue delay after being notified/informed by the exporting country CA. Efforts should be made to minimise disruptions to trade while discrepancies are rectified,
 - c. Promptly communicate to the exporting country CA any issues encountered,
 - d. Inform the exporting country CA once the update to the list is completed.
23. If an importing country CA plans to introduce any amendments to the requirements or application process for the establishment list, the importing country CA should provide explanations and pertinent information in accordance with paragraph 13 a. and b.
24. The exporting country CA should provide timely notifications to the importing country CA of required amendments to establishment lists, including additions, de-listing and updates to information. This information exchange should not disrupt trade.

Section 10 – Suspensions and de-listing

25. The importing country CA should clearly define and communicate the criteria and processes for suspension, de-listing, reinstatement and re-listing of establishments.
26. When an establishment is suspended or de-listed:
 - by the exporting country, the exporting country CA should promptly inform the importing country CA, including the rationale and supporting information for the decision.
 - by the importing country, the importing country CA should promptly inform the exporting country CA, including the rationale and supporting information for the decision.
 - the exporting and importing countries should agree on timeframes for products in storage and transit to manage and mitigate disruption to trade.