Annex II(E2)
Management System Checklist
[for FSMS certification (based on ISO 22003-1: 2022)]

The food safety management system certification body shall complete the following checklist, which will be used for the assessment of the food safety management system certification body's conformity with HKAS and HKCAS accreditation requirements.

This checklist consists of questions based on the requirements of ISO 22003-1: 2022 and HKCAS SC-06 (Issue No. 7). For further information, please refer to the corresponding document and clause as listed in the second column.

The food safety management system certification body shall indicate in the 'QM Clause' column, for every question, the clause(s) in its management system manual, operation procedures or other related documentation which can demonstrate the food safety management system certification body's conformity with the requirement.

The column headed 'OK' is for internal use of HKAS Executive.

A softcopy of this completed checklist shall be provided to HKAS Executive by email or other means.

ISO 22003-1: 2022 Requirements	Clause	OK	QM/ Procedure Clause	Remarks / Questions to be asked at certification body
REQUIREMENTS FOR CERTIFICATION BODIES				
Resource requirements				
Does your certification body define certification functions for which competence shall be identified in accordance with Annex C of ISO 22003-1: 2022?	7.1.1	☐		
Does your certification body define technical areas in accordance with Annex A of ISO 22003-1: 2022?	7.1.2	☐		
Does your certification body evaluate, in particular, the individual's knowledge relating to food safety, including knowledge of specific prerequisite programmes (PRPs), food safety hazards and control measures related to the categories within which the certification body personnel operate?	7.1.3	☐		
Do evaluators of your certification body have knowledge of (one or more) evaluation methods (see ISO/IEC 17021-1: 2015, Annex B)? Does the evaluators demonstrate the ability to apply them?		☐		
Information requirements				
Do certification documents of your certification body identify in detail the categories and subcategories in Table A.1 of ISO 22003-1: 2022 to which the FSMS applies?	8.2	☐		
Does your certification body not authorize the use of the FSMS certification mark on the product and the product packaging? Product packaging, refers to ISO/IEC 17021-1:2015, clause 8.3, shall cover all product packaging, both primary packaging (which contains the product) and any outer or secondary packaging.	8.3	☐		

ISO 22003-1: 2022 Requirements	Clause	OK	QM/ Procedure Clause	Remarks / Questions to be asked at certification body
Does your certification body not permit the use of any statement on product packaging that the client has a certified FSMS? This includes all product packaging, both primary packaging (which contains the product) and any outer or secondary packaging.	8.4	☐		
Process requirements				
Does your certification body require the applicant organization to provide the information concerning products and processes relevant to determination of the audit duration, as per Annexes A and B of ISO 22003-1: 2022?	9.1.1	☐		
Does your certification body use Annex A of ISO 22003-1: 2022 to define the relevant scope for the organization applying for certification?	9.1.2.2	☐		
Does the scope statement:				
- identify the category(s) or subcategory(s) in scope of certification for each site or sites; and		☐		
- briefly describe the main types of activities/processes for the products and/or services that are audited by the certifying body?		☐		
Does the defined scope of certification not:	9.1.2.3			
- be misleading;		☐		
- exclude activities, processes, products or services from the scope of certification when those activities, processes, products or services can have an influence on the food safety of the end products as defined by the legal responsibility of the organisations' activities; and		☐		
- include any promotional statements, brands or claims?		☐		

ISO 22003-1: 2022 Requirements	Clause	OK	QM/ Procedure Clause	Remarks / Questions to be asked at certification body
Does your certification body have a process for choosing the audit timing and season, so that the audit team has the opportunity of auditing the organization operating on a representative number of product lines and/or services covered by the scope of certification?	9.1.3.2	☐		
Does your certification body have documented procedures for determining audit time?	9.1.4.2	☐		
For each client, does your certification body determine the time needed to plan and accomplish a complete and effective audit of the client's FSMS?		☐		
In determining the audit duration, does your certification body use the methodology described in Annex B of ISO 22003-1: 2022?		☐		
Does your certification body record the audit time determined and the justification for the determination?		☐		
In determining and documenting audit time needed, does your certification body determine:	9.1.4.3			
(a) the time for audit preparation;		☐		
(b) the minimum duration for auditing for each site for on-site or remote auditing, as specified in Clauses B.1, B.2 and B.3 and Table B.1 of ISO 22003-1: 2022;		☐		
(c) the time for reporting and, if applicable, conducting post-audit activities;		☐		
(d) where additional meetings are necessary (e.g. review meetings, coordination, audit team briefing), an increase in audit time can be required; and		☐		
(e) where applicable and agreed, the time needed to ensure effective remote auditing or use of information and communication technology (ICT)?		☐		

ISO 22003-1: 2022 Requirements	Clause	OK	QM/ Procedure Clause	Remarks / Questions to be asked at certification body
When multi-site sampling is undertaken, does sampling of multi-site organizations cover all activities (see the criteria given in 9.1.5.3 of ISO 22003-1: 2022)?	9.1.5.2	☐		
Does your certification body demonstrate that the sampling of sites does not undermine effective auditing?	9.1.5.3	☐		
When multi-site sampling is undertaken, does your certification body justify and document the rationale based on the following conditions:				
(a) sites are operating under one centrally controlled and administered FSMS;		☐		
(b) sites subject to sampling are similar (food chain subcategory, geographical location, processes and technologies, size and complexity, regulatory and statutory requirements, customer requirements, food safety hazards and control measures);		☐		
(c) the central function is part of the organization, clearly identified and not subcontracted to an external organization;		☐		
(d) all sites have a legal or contractual link with the central function;		☐		
(e) the central function has organizational authority to define, establish and maintain the FSMS;		☐		
(f) all sites are subject to the organization's internal audit programme and have been audited;		☐		
(g) audit findings at a site are considered indicative of the entire FSMS and corrective actions are implemented accordingly;		☐		
(h) the central function is responsible for ensuring that outcomes of performance evaluation and customer complaints from all sites are collected and analysed;		☐		
(i) the organization's FSMS is subject to central management review;		☐		
(j) the central function has authority to initiate continual improvement of the FSMS?		☐		

ISO 22003-1: 2022 Requirements	Clause	OK	QM/ Procedure Clause	Remarks / Questions to be asked at certification body
The use of multi-site sampling is permitted for categories A and B. Sampling may be applied to multi-site organizations, with the minimum sample size being the square root of the total number of sites: $\sqrt{}(x)$, rounded up to the next whole number. Does your certification body take the square root sample per risk category based on production complexity of the sites (e.g. open field plant production, perennial plant production, indoor production, open field livestock production, indoor livestock production)?	9.1.5.4	☐		
The use of multi-site sampling is permitted for categories F and G, and only for re-heating-type facilities (e.g. event catering, coffee shops, pubs) for category E and only for facilities with limited preparation or cooking (e.g. re-heating, frying) (see Table A.1 of ISO 22003-1: 2022). For organizations with 20 sites or fewer, does your certification body audit all sites? For organizations with more than 20 sites, does your certification determine the minimum number of sites to be sampled be 20 plus the square root of the total number of other sites: $y = 20 + \sqrt{}(x - 20)$, rounded up to the next whole number? This applies to the initial certification, to surveillance and to recertification audits.		☐		
Does your certification body not use multi-site sampling for any categories other than categories A, B, E, F and G?		☐		
Where multi-site sampling is permitted, does your certification body ensure (e.g. via contractual arrangements) that the organization has conducted an internal audit for each site within one year prior to certification and when applicable the effectiveness of corrective actions is available? Following certification, does your certification body ensure that the annual internal audit covers all sites of the organization included in the certification scope of the multi-site organization and ongoing effectiveness of corrective actions is demonstrated?	9.1.5.5	☐		

ISO 22003-1: 2022 Requirements	Clause	OK	QM/ Procedure Clause	Remarks / Questions to be asked at certification body
Where multi-site sampling is permitted, does your certification body define and utilize a sampling programme to ensure an effective audit of the FSMS where the following conditions apply?	9.1.5.6			
(a) At least annually, does your certification body perform an audit of the central function for the FSMS prior to the sampled site audits?		☐		
(b) At least annually, does your certification body perform audits on the required number of sampled sites?		☐		
(c) Does your certification body assess audit findings of the sampled sites to ascertain if these indicate an overall FSMS deficiency and therefore can be applicable to some or all other sites?		☐		
(d) Where audit findings of the sampled sites are considered indicative of the entire FSMS, does your certification body ensure that corrective actions are implemented accordingly?		☐		
(e) For organizations with 20 sites or fewer, does your certification body audit all sites?		☐		
Does your certification body increase the size of sample or terminate the site sampling where the FSMS subject to certification does not indicate the ability to achieve the intended results?		☐		
Does your certification body conduct the sampling partly selective and partly random to result in a representative range of different sites being selected? Does your certification body ensure that all processes covered by the scope of certification would be audited?	9.1.5.7	☐		
Does your certification body select at least 25 % of the sample at random? Does your certification body select the remainder so that the differences among the sites selected over the period of validity of the certification are as large as possible?		☐		

ISO 22003-1: 2022 Requirements	Clause	OK	QM/ Procedure Clause	Remarks / Questions to be asked at certification body
Does your certification body consider the following aspects for the site selection:	9.1.5.7 (Cont'd)			
(a) results of internal audits, management reviews or previous audits;		☐		
(b) records of complaints, product withdrawals/recalls, and other relevant aspects of corrective action;		☐		
(c) variations in the site characteristics;		☐		
(d) other relevant changes since the last audit?		☐		
If any site has a major nonconformity and satisfactory corrective action have not been implemented in the agreed time frame, does your certification body not grant or maintain for the whole multi-site organization pending satisfactory corrective action?	9.1.5.8	☐		
Does your certification body identify and include in the scope of certification the processes of the FSMS implemented at each sampled site?	9.1.5.9	☐		
The objectives of stage 1 are to provide a focus for the planning of stage 2 of the initial audit by gaining an understanding of the organization's FSMS and the organization's state of preparedness for stage 2. Does your certification body review the extent to which:	9.3.2			
(a) the organization has identified PRPs that are appropriate to the business (e.g. regulatory, statutory, customer and certification scheme requirements);		☐		
(b) the FSMS includes adequate processes and methods for the identification and assessment of the organization's food safety hazards, and subsequent selection and categorization of control measures (combinations);		☐		
(c) the FSMS includes adequate processes and methods for the identification and implementation of relevant food safety legislation;		☐		
(d) the FSMS is designed to achieve the organization's food safety policy;		☐		

ISO 22003-1: 2022 Requirements	Clause	OK	QM/ Procedure Clause	Remarks / Questions to be asked at certification body
(e) the FSMS implementation programme justifies proceeding to stage 2;	9.3.2 (Cont'd)	☐		
(f) the validation of control measures, verification of activities and improvement programmes conform to the requirements of the FSMS standard;		☐		
(g) the FSMS documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties; and		☐		
(h) there is any additional documentation which needs to be reviewed and/or information which needs to be obtained in advance?		☐		
Where an organization has implemented externally developed elements of a FSMS, does your certification body review the documentation included in the FSMS in stage 1 to determine if the combination of control measures:	9.3.3			
- is suitable for the organization;		☐		
- was developed in conformity to the requirements of ISO 22000 or other sets of specified FSMS requirements; and		☐		
- is kept up to date?		☐		
Does your certification body check the availability of relevant authorizations when collecting the information regarding the compliance to regulatory aspects?	9.3.4	☐		
For FSMS, does your certification body carry out stage 1 at the client's premises in order to achieve the objectives stated above? In exceptional circumstances or events, all or part of stage 1 can take place off-site or remotely through the use of ICT, does your certification body provide the justification? Does your certification body provide the evidence demonstrating that stage 1 objectives are fully achieved?	9.3.5	☐		
The interval between stage 1 and stage 2 shall not be longer than six months. Does your certification body repeat stage 1 if a longer interval is needed?	9.3.6	☐		

ISO 22003-1: 2022 Requirements	Clause	OK	QM/ Procedure Clause	Remarks / Questions to be asked at certification body
Where your certification body conducts unannounced audits as part of surveillance activities, does your certification body describe and make known in advance to the certified clients the conditions under which such audits will be organized and conducted?	9.6.2	☐		

Regulations for HKAS Accreditation	Clause	OK	QM/Procedure Clause	Remarks / Questions to be asked at certification body
Does your certification body ensure that a lead auditor or an auditor have at least an associate degree or higher diploma qualification in an engineering, technology or science discipline from a recognised educational institution in Hong Kong, or equivalent qualification?	HKCAS SC-06 3.1	☐		
Does your certification body evaluate the performance of every lead auditor and auditor on-site at least once every 3 years? Does the evaluation cover all aspects of the activities that the auditors have been authorised by your certification body to perform? Does your certification body take any corrective actions if there is any doubt on their competence?	HKCAS SC-06 3.2	☐		
Certification decisions may be made by a staff member or a committee. In case the certification decision is made by a committee, does your certification body ensure that the committee members have a level of knowledge and experience sufficient for making a sound decision based on the results or information obtained from the auditing processes? Does your certification body have documented procedures and criteria for the committee to make certification decisions and the committee members are conversant with the procedures and criteria? It may be necessary to provide appropriate training to committee members for such conversance. Does your certification body keep detailed records of the factors considered by the committee and the deliberation?	HKCAS SC-06 3.3	☐		
Does your certification body specify the information to be provided by an applicant organisation which applies for its certification such as relevant information of the applicant organisation, desired scope of the certification, copies of valid appropriate licence(s)/permit(s) issued by the relevant government departments/bureaux, documents describing the process lines (e.g. flow diagram of the production process, detailed process description, operation procedure etc.) and quality assurance measures, all outsourced processes, HACCP (Hazard Analysis and Critical Control Point) studies, the number of shifts and information concerning the use of consultancy relating to the management system? Upon receiving an application, does your certification body review and check whether sufficient information has been provided by the organisation and ask for supplementary information if necessary?	HKCAS SC-06 4.1	☐		

Regulations for HKAS Accreditation	Clause	OK	QM/Procedure Clause	Remarks / Questions to be asked at certification body
Does your certification body determine the interval between stage 1 and stage 2 audits and only conduct stage 2 audit after the findings identified in the stage 1 audit have been adequately resolved by the applicant organisation? Does your certification body justify the interval between stage 1 and stage 2 audits?	HKCAS SC-06 4.2	☐		

Policy for HKAS Accreditation	Clause	OK	Supporting Document	Remarks / Questions to be asked at certification body
HKAS Policy on FSMS Certification Scheme (applicable to a certification body offering a third-party certification service on FSMS in respect of a certification scheme)				
Does the certification scheme define the classification of food chain clusters, categories and sub-categories in line with Annex A of ISO 22003-1: 2022? Where the certification scheme has established its own rules for determination for clusters/categories/subcategories, are the scheme rules not less than those required in Annex A of ISO 22003-1: 2022 as a common basis?	HKCAS SC-06 Annex B, B.2	☐		
Annex B of ISO 22003-1: 2022 specifies the methodology of determining the audit duration. Where the certification scheme has established its own rules for determination for audit duration, are the scheme rules not less than those required in Annex B of ISO 22003-1: 2022 as a minimum?	HKCAS SC-06 Annex B, B.3	☐		