

FSI 崑凱檢驗科技股份國際有限公司

HACCP/ISO 22000/FSSC 22000 評鑑追查人天數一覽表

(ISO 22003-1 2022 附錄 B 最低初次稽核時間)

Audit time calculation for HACCP/ISO 22000/FSSC 22000

Annex B of ISO 22003-1:2022

食品鏈 類別 Category Of Food	T _b 基本現場 稽核時間 Basic on-site time required (人天) (MD)	T _h 對每一額外 HACCP 審視 For every extra HACCP model (人天) (MD)	T _{FTE} 員工數量 Number of Employee (人天) (MD)	每一需訪視 之額外場區 Extra on-site	(for FSSC) PRP 對每一額外 FSSC22000 審視 For every extra FSSC22000 model (人天)(MD)	(for FSSC) P 準備和報告時間 Preparation and reporting time (人天) (MD)	(for FSSC) 設有單獨總部的組織 Organizations with a separate head office
A	1	0.25					
B	1	0.25					
C	2.0	0.50					
D	1.0	0.50					
E	1.5	0.50					
F	1.0	0.50					
G	1.5	0.25					
H	1.5	0.25					
I	1.5	0.50					
J	1.5	0.50					
K	2.0	0.50					
			1~5=0 6~49=0.5 50~99=1.0 100~199=1.5 200~499=2.0 500~999=2.5 >1,000=3.0	1. 每一需訪視 之額外場區： 最低現場稽核 時間之 50% Extra on-site: 50% of the minimal on-site time required	依組織規模和複雜 性判斷 Organization size and complexity 1. 若< 250 FTE 且< 3 份 HACCP =1.0/8 工時 2. 若≥250 FTE 或< 3 份 HACCP =1.5/12 工 時	現場稽核時間最 少增加 25% (0.25/2 working hours; 0.5/4 working hours)	若總部非與作業現場 同一區域，現場最少 0.5/4 工時，最多為現 場稽核時間之 80%/ 每 個其製造廠場 Organizations with a separate head office the minimum time shall be 0.5 auditor day (4 working hours) maximum of 20% audit time reduction.

一、ISO 22000及HACCP稽核時間計算如下

1. 單一場區之最低稽核時間Ds = (T_D+T_H+ T_{FTE})

The minimal time required Ds= (T_D+T_H+ T_{FTE})

T_D:為基本現場稽時間，以天數計

T_D: for the basic site time, in days

T_H:為額外HACCP審視之稽核天數

T_H: Audit days for additional HACCP review

T_{FTE}:為依照每批員工數之稽核天數

T_{FTE}: the number of audit days in accordance with the number of employees per batch

1.1依循食品安全管理系統驗證機構認證規範(ISO 22003-1:2022)附錄B要求，其最低稽核時間係基於僅包含一個HACCP 審視之FSMS 稽核制定出。一個HACCP 審視相當於一具有類似危害與類似生產技術及相關的類似儲存技術的產品/服務類別之危害分析。

Following the requirements of Appendix B of the Food Safety Management System Certification Body Certification Specification (ISO 22003-1:2022), the minimum audit time is based on the FSMS audit that contains only one HACCP review. The nuclear is developed. A HACCP

review is equivalent to a hazard analysis of a product/service category with similar hazards and similar production techniques and associated similar storage technologies.

1.2組織實現產品及/或服務之現場稽核之最低時間為全部最低稽核時間的50%(適用於所有類型之稽核)。

The minimum time for the organization to implement on-site audits of products and/or services is 50% of all minimum audit time (applicable

to all types of audits).

1.3 參與任何食品安全層面之員工數，應以全職相當的員工數(FTE)表示。當組織以輪班制調派員工，而產品及/或服務相同，則FTE人數係以主輪職員工(包括季節性員工)加上辦公室員工計算。

The number of employees participating in any food safety level should be expressed in terms of full-time equivalent staff (FTE). When an

organization deploys employees on a shift basis and the products and/or services are the same, the FTE number is calculated by the main

rotation staff (including seasonal employees) plus office staff.

1.4 若某一特定客戶組織之稽核範圍涵蓋類別不只一種，則稽核期間計算應採納最高建議之基本稽核時間。每一個HACCP 審視均需有額外時間(即每一個HACCP 審視至少需有0.5稽核天)。

If the audit scope of a particular customer organization covers more than one category, the audit period calculation should adopt the highest

recommended base audit time. Each HACCP review requires additional time (ie, at least 0.5 audit days per HACCP review).

1.5 除主場區外，每一場區之稽核時間依表B.1 計算出，每個場區至少1 稽核天。如已適當文件化並有正當理由，對於較不複雜的組織，可依員工數、組織規模及/或產品量，或在各類別範圍內之Ts 時間少於1.5 稽核天，則可縮減稽核時間。

Except for the main area, the audit time of each area is calculated according to Table B.1, and each field has at least 1 audit day. If properly

documented and justified, the audit time can be reduced for less complex organizations based on the number of employees, the size of the

organization and/or the amount of products, or the Ts time in each category is less than 1.5 audit days. .

1.6 一般情況下每一場區之稽核人天數應符合食品安全管理系統驗證機構認證規範(ISO 22003-1:2022)附錄B要求。第一階段至少安排

1人天，依廠場HACCP複雜程度增加人數，在計算過程中如對每一額外HACCP審視為5人天時，則第一階段人天安排再增加1人天。

Under normal circumstances, the number of auditors in each area should meet the requirements of Appendix B of the Food Safety Management System Certification Body Certification (ISO 22003-1:2022). The first phase will be arranged for at least one person's day.

According to the complexity of the HACCP complexity of the plant, if the additional HACCP is considered as 5 person-days in the calculation process, the first phase of the person will be increased by one person.

1.7 最低現場時間包括初次驗證之第1階段及第2階段（參考 ISO 22003-1:2022 及 IAF MD5:2015），但不包括準備稽核的時間及撰寫稽核報告的時間。應告知客戶第一階段稽核之結果可能導致第二階段稽核延後或取消的訊息。

The minimum on-site time includes Phase 1 and Phase 2 of the initial verification (refer to ISO 22003-1:2022 and IAF MD5:2015), but

does not include the time to prepare the audit and the time to write the audit report. The client should be informed of the results of the first

phase audit that may result in a delay or cancellation of the second phase audit.

1.8 最低追查驗證時間須達初次驗證稽核(第一階段+第二階段)所花時間，按比例分配該組織之追查稽核時間，每年追查時間總數約為初次驗證稽核時間的三分之一，最少要有1人天(A類及B類為0.5人天)。

The minimum tracing verification time must be the time taken for the initial verification audit (Phase 1 + Phase 2), and the organization's

tracing audit time is prorated. The total number of tracing times per year is approximately. One-third of the initial

verification audit time

must be at least 1 person-days(0.5 person-days for category A & B).

1.9 重新驗證時間須達初次稽核(第一階段+第二階段)時間的三分之二，最少要有1人天(A類及B類為0.5人天)。但要確保其品質管理系統在三年期間內證實

已發揮效果。

The revalidation time must be two-thirds of the initial audit (Phase 1 + Phase 2), with a minimum of 1 person day(0.5 person-days for category A & B). But make sure that its

quality management system is proven to be effective over a three-year period.

1.10 若申請單位分別有不同廠區時，則需分開審視各廠區生產產品、HACCP 數與員工數，並分別計算各廠區之人天數。

Except for the main area, the audit time of each area is calculated according to Table B.1, and each field has at least 1 audit day. If properly

documented and justified, the audit time can be reduced for less complex organizations based on the number of employees, the size of the

organization and/or the amount of products, or the Ts time in each category is less than 1.5 audit days. .

1.11 如果計算後的結果有小數，須調整日數到最近的半日或維持小數但不可捨去。(例如：5.3 個稽核日調整為 5.5 個稽核日，5.2 個稽核日調整為 5.5 個稽核日或維持 5.2 個稽核日)

If the calculated result has a decimal, the number of days must be adjusted to the nearest half day (for example, 5.3 audit days are adjusted to 5.5 audit days, 5.2 audit days are adjusted to 5.5 audit days or maintained 5.2 audit days)

1.12 額外(特殊)審核可以優先進行 - 但絕不能取代年度監督/再驗證審核。應記錄這些特殊審核並上傳到 Portal 網站上。應始終遵守年度審核最少審核時間。

2. 每一額外場區之最低稽核時間 $T_m = Ts \times 50/100$

The minimal time for every extra site $T_m = Ts \times 50/100$

2.1 使用多場區之取樣只有在組織的場區超過 20 個及類別 A、B、E、F 與 G 以及場區超過 20 個且在此等類別內才可行。此抽樣適用於初次驗證、追查及重新驗證稽核。

The use of multi-field sampling is only possible in the organization's field area of more than 20 categories and categories A, B, E, F and G

and more than 20 field areas and are only feasible in these categories. This sampling applies to the initial verification, tracing and

revalidation audits as well as for initial verification and tracing audits.

2.2 驗證機構提供多場區驗證時，在下列情形下驗證機構應使用取樣計畫，以確保有效之 FSMS 稽核。

When the certification body conduct multi-sites audit, the certification body should use a sampling plan under the following conditions to ensure effective FSMS audit.

2.3 20 個以上之場區取樣比例應為 5 個場區取 1 個，所有的場區應隨機選擇，且所有取樣之場區在稽核後不能有不符合者(即無法符

合 ISO22000 的驗證門檻)。

Sampling area of more than 20 sites should be taken as 1 for 5 sites, all sites should be randomly selected, and all sampling areas should

not have non-compliance after audit (that is, they can not meet the verification threshold of ISO22000).

2.4 追查稽核的最低時間為初次驗證稽核時間的三分之一，但至少為 1 稽核天(類別 A 與 B 為 0.5 稽核天)。

重新驗證之最低稽核時間為初次驗證稽核時間的三分之二，但至少為 1 稽核天(類別 A 與 B 為 0.5 稽核天)。如已適當文件化並有正當理由，則對於較不複雜的組織，可依員工數、組織規格及/或產品量，或在各類別範圍內之初次稽核最低時間少於 1.5 稽核天，則可縮減至最低稽核時間。

The minimum time to track the audit is one-third of the initial verification audit time, but at least 1 audit day (category A and B are 0.5

audit days). The minimum audit time for revalidation is two-thirds of the initial verification audit time, but at least 1 audit day (category A

and B are 0.5 audit days). If properly documented and justified, for less complex organizations, depending on the number of employees,

organizational specifications and/or product quantities, or the initial audit minimum time within each category is less than 1.5 audit days, Reduced to the minimum audit time.

二、FSSC22000稽核時間計算如下

1審核人天 Auditor day

1.1每個稽核日工時通常為八小時，可以包括也可以不包括午飯時間，具體取決於當地法令。

The duration of an audit day normally is eight (8) hours and may or may not include a lunch break depending upon local legislation.

1.2現場稽核工時應在稽核員於現場展開 FSSC 22000 稽核的工時中載明。

The on-site audit duration shall be stated in auditor working hours indicating the time spent at the site conducting the FSSC 22000 audit.

1.3FSSC 22000 的審核時間計算應由驗證機構記錄，包括按照最少審核時間增減時間的理由；

The audit time calculation for FSSC 22000 should be recorded by the certification body, including the reasons for adding or subtracting time based on the minimum audit time

1.4現場審核時間應以審核員現場花費工作時間為準，應與審核計劃相符，並應記錄發生的偏差（包括原因）；

The on-site audit time should be based on the auditor's on-site working time, which should be consistent with the

audit plan, and any deviations (including reasons) should be recorded.

1.5 現場審核時間不包括計劃、報告或差旅活動時間，僅包括實際的現場審核時間；

On-site audit time does not include planning, reporting or travel activity time, only actual on-site audit time.

1.6 現場審核時間僅適用於完全合格的註冊 FSSC 22000 審核員；

On-site audit hours are only available to fully qualified registered FSSC 22000 auditors.

1.7 當 FSSC 22000 審核與其他食品安全審核相結合或整合進行結合審核時，報告中所述的審核時間應為結合審核總時間，並應與審核計劃相匹配。因此，總審核時間長於單獨 FSSC 22000 審核時間。這被視為審核時間增加，其原因應理由充分。

When the FSSC 22000 audit is combined or integrated with other food safety audits to perform a combined audit, the audit time stated in the report should be the total combined audit time and should be compared with the audit time. Therefore, the total audit time is longer than the individual FSSC 22000 audit time. This is considered an increase in review time and the reasons should be well-justified.

2 聯合稽核 Joint audits

2.1 若 FSSC 22000 稽核與其他稽核一同執行，則應載明 FSSC22000 稽核的規定時間之計算。

Where the FSSC 22000 audit is undertaken with other audits, then a calculation for the time-allowed of the FSSC 22000 audit only shall be stated.

3 基礎審核時間計算（單一場所）總的現場審核時間（針對單一場所）定義為 $D_s + TFSSC$ ，其中：

Calculation of basic audit time (single site) The total on-site audit time (for a single site) is defined as $D_s + TFSSC$

a) $D_s = (TD + TH + TFTE)$ ，根據 ISO 22003-1:2022 計算

3.1b) TFSSC 的計算方法如下 TFSSC is calculated as follows :

3.1.1 方案要求除 ISO 22003-1: 2022 條款 9.1.4 和附錄 B 中規定的稽核時間(包括準備、現場稽核和報告)外，驗證機構 (CB)

應增加 0.5-1 個稽核人天 (4-8 個工時，具體取決於如下規定的組織規模) 以便對相關前提方案進行稽核。

The Scheme requires that in addition to the audit time (which includes preparation, on-site audit and reporting) as stipulated in clause 9.1.4 and Annex B of ISO 22003-1:2022, the CB shall add 0.5 – 1 auditor day (4-8 working hours, depending on the size of the organization as specified below) for the audit on the implementation of the relevant Pre-Requisite Program(s).

3.1.2 這適用於正式評鑑、追蹤評鑑（通知或不通知）和重新評鑑。

This is applicable to initial, surveillance (announced or unannounced) and recertification audits.

3.1.3 組織規模和複雜性 Organization size and complexity :

3.1.3.1 現場增加 1 個稽核人天 (8 個工時) (包括食品欺詐預防和食品防護的評估)，當企業未達到：

1 auditor day (8 working hours) on-site (including food fraud prevention and food defense assessment) when the company has less than:

3.1.3.1.1 250 名全日制員工 (FTE) 以及

250 FTE and

3.1.3.1.2 3 項 HACCP 項目。

3 HACCP studies

3.1.3.2 現場增加 1.5 個審核人天 (12 個工時) (包括食品欺詐和食品防護的評估)，當企業達到：

1.5 auditor day (12 working hours) on-site (including food fraud prevention and food defense assessment) when the organization has:

3.1.3.2.1 250 名全日制員工 (FTE) 或以上；或者

250 FTE or more; or

3.1.3.2.2 3 項 HACCP 專案或更多。

3 HACCP studies or more.

3.2 準備和報告時間應不包括在現場稽核時間內 Preparation and reporting time should not be included in the on-site audit time

3.2.1 應在 FSSC 22000 現場稽核時間中至少增加 0.25 個稽核人天 (2 個工時) 用於稽核準備。

At least 0.25 auditor day (2 working hours) shall be added to the FSSC 22000 on-site audit time for audit preparation.

3.2.2 應在 FSSC 22000 現場稽核時間中至少增加 1 個附加的稽核人天 (8 個工時) 用於進行編寫稽核報告。

At least 1 auditor day (8 working hours) additional shall be added to the FSSC 22000 on-site audit time for audit reporting.

3.3 口譯員 Use of an interpreter :

3.3.1 如果稽核團隊需要口譯員翻譯說明，則應在 FSSC 22000 稽核時間中至少增加 0.5 個現場稽核人天(4 個工時)

At least 0.5 auditor day (4 working hours) additional on-site audit time shall be added to the FSSC 22000 audit time when an interpreter is required to support the audit team.

3.4 非現場儲存 Off-site storage :

3.4.1 應在 FSSC 22000 稽核時間中至少為每個非現場貯存設施增加 0.25 個現場稽核人天(2 個工時)。

At least 0.25 auditor day (2 working hours) additional on-site audit time shall be added to the FSSC 22000 audit time for each off-site storage facility.

3.5 設有單獨總部的組織：

Organizations with a separate head office :

3.5.1 對於某些驗證相關職能由不在生產現場的總部控制的組織，現場的最短時間應為 0.5 個稽核人天 (4 個工時)，以便在總部對驗證相關職能進行稽核。

For organizations where some functions pertinent to the certification are controlled by a head office separate to the manufacturing site(s), the minimum time shall be 0.5 auditor day (4 working hours) on-site to audit the functions pertinent to the certification at the head office.

3.5.2如果總部的負責人來到生產現場參加稽核，則不應額外計算稽核時間。

When the responsible person from the head office attends the audit at manufacturing site, no extra audit time is calculated.

3.5.3共用職能由（非現場）總部控制的每一個集團下屬生產現場最多可允許 20% 的稽核時間壓縮。20% 稽核時間壓縮適用於附錄 B 的 ISO 22003-1:2022 中所示的最短稽核時間 (Ds)。

A maximum of 20% audit time reduction can be allowed for each of the single manufacturing sites belonging to the group where the shared functions are controlled by the (off-site) head office. The 20% audit time reduction is applied to the minimum audit time (Ds) as shown in ISO 22003-1:2022, Annex B.

3.6展開非現場活動的組織：

Organizations with off-site activities :

3.6.1在展開非現場活動的生產企業（即一個或多個流程步驟發生於第二現場）中，50% 基於 Ts 的審核時間壓縮適用於每個第二現場計算的最短總現場稽核時間。

In manufacturing organizations with off-site activities where one or more process steps take place at a secondary site, a 50% audit time reduction based on Ts is applied for the minimum calculated total on-site audit time for each secondary site.

4 轉換到 FSSC 22000

Transition to FSSC 22000

4.1在從 Dutch HACCP、ISO 22000 或 GFSI 認可的認證轉換到 FSSC 22000 認證時，FSSC 22000 最少認證現場審核時間應為初次

認證審核時間的 2/3，最短 1 個現場審核人天（8 個工時）加上加上定義的 TFSSC。通過轉換審核則應頒發 FSSC 22000 驗證證書，有效期為三（3）年，詳「驗證作業程序」(WKB3-02)。

When converting from Dutch HACCP, ISO 22000 or equivalent GFSI-approved verification to FSSC 22000 verification, the minimum FSSC22000 verification site audit time shall be two thirds of the initial verification audit time, and at least 1 on-site auditor day Man-hours) plus TFSSC. Upon conversion audit, a FSSC 22000 verification certificate shall be issued with a validity of three (3) years, Verification Procedure WKB3-02.

4.2只有當組織擁有有效的 ISO 22000 或 FSSC 22000 證書和有效的 ISO 9001 證書時，才能轉換到 FSSC 22000-質量。在這種情況下，審核時間是初始綜合審核時間的三分之二（見 4.3.4）加上 TFSSC。

The organization can only switch to FSSC 22000-quality if it has a valid ISO 22000 or FSSC 22000 certificate and a valid ISO 9001 certificate. In this case, the audit time is two-thirds of the initial comprehensive audit time (see 4.3.4) plus TFSSC.

5 稽核時間計算 Audit time calculation :

5.1 稽核時間計算應：

The audit time calculation shall:

5.1.1 包含在報告和稽核時間計算表中，

be included in the report and audit time calculation sheet,

5.1.2 滿足 ISO 22003-1:2022 附錄 B 中顯示的稽核時間計算公式 即 $(Ds = (D + H + FTE))$ 加上 FSSC 22000 附加稽核時間。
match the audit time calculation tool shown in ISO 22003-1:2022, Annex B
i. e. $(Ds = (D + H + FTE))$ plus the additional FSSC 22000 audit time.

5.2如果恰當記錄並有合理的理由，依照 ISO 22003-1:2022、附錄 B，對於 Ts 時間短於 1.5 個稽核人天且並不太複雜的組織，則可以縮短其 Ts 稽核時間。縮短的 Ts 稽核時間不得少於 0.25 個稽核人天(2 個工時)。縮短不適用於 FSSC 稽核時間寬限，如本附錄第 2.1 節所示。

When properly documented and justified, a reduction of the Ts audit time can be made for a less complex organization having a Ts time less than 1,5 auditor days, in accordance with ISO 22003-1:2022, Annex B. The reduced Ts audit time can never be less than 0,25 auditor day (2 working hours). The reduction cannot be applied on the FSSC audit time allowance as shown in section 2.1 of this Annex.

5.3稽核時間計算的判定，包括任何申請的減少（參見上文）或增加，應包括在稽核報告中。

Justification of the audit duration calculation including any applied reduction (see above) or increase shall be included in the audit report.

*當客戶同時申請 ISO22000 及 ISO9001 時，人天計算依循『ISO9001 評鑑人天數一覽表』(WKB3-01-06)及『HACCP/ISO 22000/FSSC 22000 評鑑追查人天數一覽表』(WKB3-01-07)個別計算後，相加再進位至尾數為 0.5 人天或整數人天。

When a customer applies for ISO22000 and ISO9001 at the same time, the calculation of man-days is based on the "List of man-days for ISO9001 assessment" (WKB3-01-06) and the "List of man-days for HACCP/ISO 22000/FSSC 22000 assessment" (WKB3-01-07) after individual calculations, add them up and round to the end of 0.5 person-days or an integer number of person-days.