

SoHO Coordination Board (SCB)

Annex inspection guidelines

A model for risk-based inspection planning of SOHO establishments:

Contents

Standards.....	2
How should I fill in the risk matrix (Annex 1)	3
Additional risk factors to consider	3
Annex 1 Risk Matrix.....	4

Annex inspection guidelines

A model for risk-based inspection planning of SOHO establishments:

Standards

Following the inspection referred to in Article 25(2), point (e), SoHO competent authorities shall carry out periodic inspections pursuant to Article 27 paragraph 2, point (a), so that the interval between two on-site inspections shall not exceed, in any event, 4 years. The frequency of inspections shall take account of:

- (a) identified risks associated with the type of SoHO that are subject to the SoHO establishment authorisation and the SoHO activities carried out;
- (b) the SoHO establishments' past record as regards the outcome of previous inspections and their compliance with this Regulation;
- (c) the certification or accreditation by international bodies, where relevant;
- (d) the reliability and effectiveness of the quality management system referred to in Article 37. (Art. 27.9)

For a Competent Authority (CA) to meet its obligations under the Regulation (EU) 2024/1938, systems and procedures for the scheduling and management of an effective inspection program will need to be in place. The Inspection Guidelines recommend that CAs implement policies and procedures that will facilitate a risk-based approach to inspection scheduling.

The advantages of scheduling routine inspections based on risks are significant:

- enables establishments with higher risk to be identified and prioritized in the inspection schedule – ensuring public safety and confidence.
- ensures that the resources required to conduct the routine inspections (e.g. number of inspectors, technical expertise and administrative support) are identified and planned for in advance. If resources are needed for a non-routine inspection, routine inspections of establishments classified as 'low-risk' may be postponed, and the resources reallocated to carry out the non-routine inspection.
- enables CAs to target its resources efficiently, e.g. inspections of 'low-risk' establishments may be conducted within a shorter time frame (e.g. half a day) and with a smaller inspection team compared to a 'high-risk' establishment. In exceptional cases it could also be decided to conduct desk based inspections when such inspection modes do not pose a

risk to the quality and safety of SoHO; do not prejudice the effectiveness of inspections; the protection of SoHO donors, SoHO recipients or offspring from medically assisted reproduction is respected; and the maximum interval between two on-site inspections does not exceed 4 years. Thematic inspections may also be foreseen.

- To assign a risk rating, CAs need to understand each establishment's activities and characteristics as well as the factors that present the highest risks to public safety. Factors that allow the assignment of a risk rating include:
 - intrinsic risk, which depends on:
 - the complexity of the establishment, its processes and products.
 - if the SoHO handled by the establishment are listed as critical and/or if the establishment itself is listed as critical in the Member State.
 - compliance history of the establishment.

The use of a risk-matrix will enable CAs to develop a risk profile for each establishment, which in turn can be used for scheduling a program of inspections based on objective criteria.

How should I fill in the risk matrix (Annex 1)?

- The risk matrix should be filled in after each routine inspection, when non-compliances and their classification have been decided on.
- If an inspection warrants a follow-up inspection, the risk matrix should be filled in only after completion of the follow-up inspection, when the inspection process is considered 'closed'.
- In case of major changes throughout the year, the risk profile may be altered, or the need for an urgent inspection could overrule the risk assessment.

Additional risk factors to consider

The tools used for assessing and recording risks should also allow other relevant risk factors to be considered which may increase or decrease an establishment's risk rating. The reasons for selecting or excluding any indicative risk factors should be recorded and may benefit from an independent review.

1. Organisational Factors

- Changes in management (e.g. new Responsible Person or new legal entity)
- Governance, corporate culture and internal communication practices
- Staffing stability (is there a high staff turnover)
- Significant changes in the QMS or indications of insufficient QMS

2. Operational Factors

- Significant changes to activities (e.g. new premises, expansion or cessation of activities)
- Number and severity of SARE
- Supply chain changes, including subcontractors

3. Compliance & Regulatory Factors

- Information from other inspectorates or government agencies

- Withdrawal or expiration of certifications and accreditations (e.g. JACIE, ISO 15189)
- History of non-compliances beyond the last inspection cycle

4. Reputational & External Factors

- Complaints from other SoHO entities, public or staff
- Media sensitivity or public visibility of activities
- Research activities with higher ethical or safety considerations

Annex 1 Risk Matrix

Part A – Preliminary Information about the establishment			
Establishment Name:			
Establishment Address:			
Authorisation Number:			
Last inspection date:			
Inspection team of last inspection:			
Person who fills in the form:			
Part B – The Intrinsic Risk associated with the establishment			
Risk Factor	Risk score	Criticality	
The Complexity*1 of the establishment, its processes and products, is regarded as: (1 not complex, 2 moderate complex, 3 very complex).	1 <input type="checkbox"/>	Complexity	1
	2 <input type="checkbox"/>	1	<input type="checkbox"/> (Low) <input type="checkbox"/> (Low) <input type="checkbox"/> (Med)
	3 <input type="checkbox"/>	2	<input type="checkbox"/> (Low) <input type="checkbox"/> (Med) <input type="checkbox"/> (High)
		3	<input type="checkbox"/> (Med) <input type="checkbox"/> (High) <input type="checkbox"/> (High)
The Criticality of the SoHO handled by the establishment, and/or the criticality of the establishment itself 1: None of the SoHO of the establishment are critical 2. At least one of the SoHO of the establishment is listed as critical but the establishment itself is not. 3. The establishment itself is listed as critical.	1 <input type="checkbox"/>	Use the above matrix and record the Intrinsic Risk associated with the establishment below: Low <input type="checkbox"/> Medium <input type="checkbox"/> High <input type="checkbox"/>	
	2 <input type="checkbox"/>		
	3 <input type="checkbox"/>		

PART C – Compliance Risk, based on this inspection

The compliance risk indicated by the most recent non-compliance profile of the establishment is:	Low <input type="checkbox"/> Medium <input type="checkbox"/> High <input type="checkbox"/>	- No Major or Critical non-compliances - 1 to 5 Major non-compliances - 1 or more Critical non-compliances* ² or more than 5 Majors <i>*² Please note that a critical non-compliance requires immediate action from the establishment. Stringent control measures should be taken by the MS to make sure these critical non-compliances are addressed correctly and in a timely manner. This is out of scope of this Risk Assessment (e.g. performing a follow-up inspection shortly after).</i>
--	---	---

PART D – The Risk Rating assigned to the establishment

Complete the matrix below by combining the Intrinsic risk score and the Compliance risk score to determine the **Risk Rating** for the establishment.

	Intrinsic Risk		
Compliance Risk	Low	Medium	High
Low	A <input type="checkbox"/>	A <input type="checkbox"/>	B <input type="checkbox"/>
Medium	A <input type="checkbox"/>	B <input type="checkbox"/>	C <input type="checkbox"/>
High	B <input type="checkbox"/>	C <input type="checkbox"/>	C <input type="checkbox"/>

The Risk Rating associated with this establishment is: A B C

PART E – The Recommended Frequency for Routine Inspections at the establishment

A	Reduced frequency: 4 years	Using the Risk Rating, the estimated re-inspection date is
B	Moderate frequency, 2 to 3 years	
C	Increased frequency, <2 years	
Override function: Insert justification if the inspection frequency cannot be accepted. This may be based on additional risks identified. The risks should be detailed here and a new proposed inspection frequency recommended:		Additional risks identified: New proposed inspection frequency:

Document the specific topics to address on the next inspection. And what kind of inspection is warranted (e.g. desk-based):			
Document any specific competence or expertise that will be required on the inspection team when performing the next routine inspection:			
Document the proposed duration and the proposed number of inspectors of the next routine inspection:			
<table border="1"> <tr> <td>Information to be included in below comment-field are particularities which should be taken into account when planning the next inspection</td> </tr> <tr> <td style="height: 50px;"></td> </tr> </table>		Information to be included in below comment-field are particularities which should be taken into account when planning the next inspection	
Information to be included in below comment-field are particularities which should be taken into account when planning the next inspection			

**1 What to take into account when scoring for Complexity:*

Establishment complexity: size/volume of activities, number of different preparations handled, number of staff and number of customers/other EU Member States supplied, import/export.

The larger the size of the establishment or the volume or the number of preparations, activities, staff or customers/other Member States supplied, the more complex it is. A small volume of activities could also be a risk (e.g. higher vulnerability to errors).

Process/product complexity: type of SoHO processed, type of activities, number of SoHO activities carried out, number of critical steps, number of open steps in the process, number of subcontractors or other.

Complex processing should be rated as higher – those requiring specific temperatures, complex equipment or technologies, those which have processing performed in open steps (in a classified environment) or those with newer processing methods.