

Risk-based inspections of Entities, Third Parties or Third Country Suppliers

Standards

SoHO competent authorities may carry out, pursuant to Article 27 (1), inspections of SoHO entities other than SoHO establishments, and of the third parties contracted, as necessary and proportionate to the risks associated with the SoHO and the SoHO activities registered for that SoHO entity, and to the SoHO entity's past compliance records (Art. 28.1).

The applicant for an importing SoHO establishment authorisation shall provide a written agreement that shall include: the right of the SoHO competent authorities to inspect the activities, including the facilities, of any third-country supplier or entity sub-contracted by that supplier, contracted by the importing SoHO establishment (Art. 48.3 (iii)).

The SoHO regulation does not require all entities, third parties or third country suppliers to be inspected, nor does it define the period within which these should be inspected.

National legislation may define requirements or frequency for these inspections, or a Competent Authority (CA) may through more stringent measures require an entity to be authorised as a SoHO establishment and include it in routine SoHO establishment inspection planning.

In general, SoHO CAs may carry out inspections of SoHO entities, third parties contracted by SoHO establishments, or third country suppliers if they consider it necessary. The below table can be used by CAs as a prompt when considering if an inspection of an entity, third party or third country supplier is required or it can be adapted to their own risk scheduling process. For several similar entities/third parties it may be sufficient to complete only one assessment for all these entities. For instance, when they operate by the same parent company, supply to the same SoHO establishment, operate under the same quality system, or when separate entities perform similar SoHO activities.

CAs should have processes in place for planning these inspections, ensuring that the inspection planning is conducted using a risk-based method.

CAs may consider that an inspection of a third country supplier is required prior to granting or refusing an importing establishment authorisation. This may be considered when routine importation is envisaged from this supplier or if this third country supplier supplies multiple importing establishments within the Member State (MS) or other EU MS's.

Note: This document is not for use in the decision making of risk-based inspections for entities/third parties/ third country suppliers related to plasma for the plasma master file (PMF).

How to decide on Inspecting Entities, Third Parties or Third Country Suppliers

CAs can consider the following prompts in the decision making for what entities, third parties or third country suppliers may require an inspection.

CAs can use the questions in the table below to consider if the entity, third party or third country supplier presents a risk and if an inspection is required. The answers to the questions can also be used to determine the timeframe within which inspection should occur and what resources should be assigned to the inspection.

Questions which can be considered as critical, have been highlighted within the table (▲). Particular consideration should be given to these questions and the subsequent risks. The CA should consider if answers to the critical questions indicate an increased risk. The more criticality that is attributed to a site may indicate that an inspection is required and potentially within a reduced time period.

Ideally inspections of entities should be performed by at least two inspectors. The resources can be assigned based on the criticality of the site and the activities which they perform.

CAs can use Chapter 4 of the SoHO Inspection Guidelines (Inspections) to assist with the performance of these inspections. Priority for inspection could be considered for entities identified as critical.

General questions
Has the site been inspected or audited previously? (by the relevant CA, importing SoHO establishment or associated establishment respectively) ▲ If yes, were there any concerns that indicate that a follow-up inspection or the addition of the third country supplier to a regular inspection schedule was required?
▲ Has it been observed on inspection at a different SoHO establishment/entity that this entity, third party or third country supplier has a poor compliance history with the SoHO activities they perform?
▲ Have many SAREs (larger than expected based on the number of activities performed) been received which relate to these sites? Has any trend in SAREs been identified which may indicate that appropriate CAPAs from previous SAREs or inspection findings have not been implemented?
▲ Have multiple recall notifications been received? Or in the case of third country suppliers this should also consider any relevant subcontractor recalls.
Is the site accredited for its activities? (e.g. JACIE; AATB; FACT; ISO15189; ISO17025)
Do other CAs want this entity, third party or third country supplier inspected?
Third Country Suppliers
Is a third country supplier supplying a critical SoHO which is otherwise not available within the MS, or other EU MS's? Note: an inspection may be required based on the criticality of the SoHO.
Is the third country supplier supplying multiple importing establishments within the MS?
Is there any onward distribution to other MS's (if known)?
Will the imported SoHO be supplied to multiple other entities? (consider the numbers supplied to each entity)
Entities and Third Parties
▲ Is this a new entity which has not performed any SoHO activities previously? (Consider the complexity of the SoHO activities)

▲ Is the entity considered a critical entity? Does this criticality also relate to the supply of other EU MS's?
Does the entity perform activities with a SoHO that is listed as critical in your MS?
Does the entity/third party: <ul style="list-style-type: none"> • Supply SoHO to multiple entities or establishments at a national or EU level? • Act as a collection site which is used by multiple establishments? • Store a large amount of SoHO or provide storage for multiple establishments? • Distribute to multiple entities/establishments in the MS or other MS's? • Perform testing for a large number of entities/establishments? i.e. donor testing, environmental monitoring, quality control testing? • Perform specific critical services to a large number of entities/establishments?
Have any accreditations/licenses/authorisations been suspended/revoked (if known)?
Is this a donor registry which facilitates the provision of SoHO to multiple MS's?
Is this a clinical outcome registry used by multiple entities in the MS or other EU MS's?

The above questions do not reflect consideration for non-routine/for-cause inspections of entities/third parties/third country suppliers as this is outside the scope of this section of guidance. However, it is recommended that the non-routine/for-cause process is considered where:

It has been observed on inspection at a different SoHO establishment/entity that this entity/third party/third country supplier's SoHO activities may pose a risk to public health.;

Another CA has communicated an issue with a SoHO or product manufactured from imported SoHO that may indicate an issue at the third country supplier (e.g. medicinal products or medical devices);

Information was received through other sources that may indicate a compliance issue or public safety threat (e.g. information from another CA such as medical devices or medicinal products or from a whistleblower);

SAREs have been received in relation to the entity/third party/third country supplier or imported SoHO which might indicate a potential threat to SoHO donors, SoHO recipients or offspring from MAR (this can include information received through the rapid alert system);

The third party/entity has been inspected recently and critical/major non compliances were observed.