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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Public Health (Attachés) Working Party on Public Health (Substances of Human Origin (SOHO))
Subject:	Working Party on Public Health 27 February 2023 - SOHO proposal - Commission presentation

Delegations will find in annex the presentation prepared by the Commission services for discussion in the Working Party on Public Health on 27 February 2023

Proposal for a Regulation on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

COM(2022) 338 final

Working Party on Public Health,
27 February 2023

Health

SoHO establishment authorisation

System and principles: articles 25 and 48

Process: articles 27 and 49

Articles 25 and 48
establish the system and the principles

Article 81 on transitional provisions for establishments currently authorised

Article 25 – Competent authorities

- Establishment of a system that allows for requests
- Possibility to authorise, as establishments, SoHO entities that do not process and store – criteria defined
- Validity throughout the EU – unless a relevant more stringent measure is in place

Article 48 – SoHO establishments

- Obligation to have a SoHO establishment authorisation before carrying out SoHO activities
- Obligation to ensure, through documented agreements, that contracted SoHO entities comply with the Regulation, accept to be audited by the SoHO establishment and inspected by the CA

See also Recital 32

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Articles 27 and 49 define the process

Article 27 – Competent authorities

- Provide guidelines and templates for SoHO establishment applications – consult SCB best practice guidelines
- On receipt of an application:
  - Acknowledge, assess including 3rd party agreements
  - Inspect (on-site system inspection)
  - Inform of outcome (without undue delay)
  - Grant or refuse authorisation – indicating which SoHO activities and any conditions
  - Assess and approve (if appropriate) in the case of changes
  - Submit authorisation information to the EU SoHO platform
- May suspend or withdraw a SoHO establishment authorisation or an authorisation for a specific activity – criteria defined
- Keep the EU SoHO platform updated with any changes

Article 49 – SoHO establishments

- Submit applications
- Inform the CA of any changes to the information provided following authorisation.

Importing SoHO entity authorisation

System and principles: articles 26 and 42

Process: articles 28 and 43

Articles 26 and 42 establish the system and the principles

Article 26 – Competent authorities

- Establishment of a system to receive and process requests
- Validity throughout the EU – unless a relevant more stringent measure is in place

Article 42 – SoHO entities

- Obligation to have an Importing SoHO entity authorisation before carrying out imports
- Exemption for plasma for the manufacture of plasma derived medicinal products (plasma master file, Directive 2003/63/EC)

Article 81 on transitional provisions for importing tissue establishments currently authorised

Note:
Obligations on Commission to adopt
- **Implementing Acts for the procedures**
- **a Delegated Act on the verification of equivalent safety and quality by the importing SoHO entities**

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Importing SoHO entity authorisation – the process

Article 28 – Competent authorities

- Provide guidelines and templates for importing SoHO entity applications – consult SCB best practice guidelines
- On receipt of an application:
  - Acknowledge, assess (including 3rd party agreements)
  - Inform of outcome (without undue delay)
  - Grant or refuse authorisation
  - Assess and approve (if appropriate) in the case of changes
  - Submit authorisation information to the SoHO platform
- May carry out authorisation in consultation with the SoHO National Authorities of other MS to which the SoHO will be distributed.
- May conduct inspections in 3rd countries – criterion defined
- May suspend or withdraw the authorisation – criteria defined
- Keep the SoHO platform updated with any changes
- Derogation for emergency imports for immediate application to specific patient

Article 43 – SoHO entities

- Submit applications
- Inform the CA of any changes to the information provided following authorisation
- Responsible for physical receipt and verification (can be delegated when for individual named patients).

Note:
Obligations on Commission to adopt
- **Implementing Acts for the procedures**

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Inspections

Articles 29, 30, 31, 32

Article 29 – Inspections of SoHO establishments

Note: Provision already exists in current legislation for blood and tissue establishments (not for tissue and cell procurement centres)

Paras 1 – 6: The System

- Possible types of inspections with criteria and cross-references (routine, unannounced, follow-up, linked to other provisions such as SoHO preparation authorisation or vigilance etc.)
- Which CA (same Member State)
- On site (and, where applicable, on the sites of third parties)
- By derogation – remote document review – criteria defined
- Carried out by inspectors meeting specific criteria (para 6)

See also Recital 25

Article 29 – Inspections of SoHO establishments contd.

Paras 7 – 9: The Procedure

- Verification of compliance with the standards defined in Articles 53, 54, 55 and 58 (concerning donor, recipient and offspring protection)
- Reference to the hierarchy of technical guidelines for the implementation of the standards – see next slide
- Inspection activities:
  - Facilities
  - Procedures
  - Documents
  - Quality management system
  - Samples and copies
  - Emergency plan
  - Enforcement action when necessary and proportionate to risk

Para 16 – consult the best practices agreed and documented by SCB

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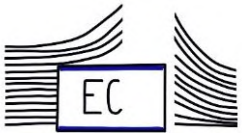
Verification of compliance with standards by implementation of technical guidelines

SoHO entities shall follow the highest available levels of standards (Art. 56 & 59):

Level 1

Commission Implementing Legislation → "where the Commission deems necessary"



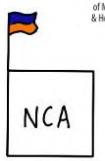
If none:

Level 2

Technical Guidance on the EU SoHO Platform → Published & updated by ECDC/EDQM

OR:

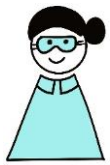
"Equivalent" Guidance → Deemed by CAs to achieve equivalent standards



If none:

Level 3

Methods based on international standards or scientific evidence



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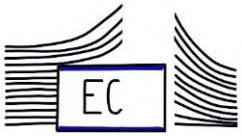


If none:

Level 2

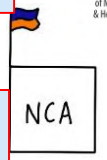
Technical Guidance on the EU SoHO Platform → Published & upda by ECDC/EDQM

"Inspectors shall accept"

OR:

"Equivalent" Guidance → Deemed by CAs to achieve equivalent standards

"Entities shall demonstrate equivalence to inspectors"



If none:

Level 3

Methods based on international standards or scientific evidence

"Entities shall demonstrate equivalence to inspectors"

Note para 8 – pre-approval of alternative guidelines

See also Recital 33

European Commission

Article 29 – Inspections of SoHO establishments contd.

Paras 10 - 12: Inspection scheduling

- Risk based scheduling – based on the activities, the past record, certifications/accreditations by international bodies, the effectiveness of the QMS
- Maximum interval between on-site inspections extended to 4 years
- Inspection prior to authorisation is the first inspection

Paras 13 - 15: Inspection follow-up

- Immediate preliminary feedback on findings (at request of SoHO establishment)
- Full report on findings – including corrective and preventive actions (CPA) or requesting the establishment to propose CPAs with timeframe
- Sharing of inspection results with other SoHO CAs when relevant

Correction!
Article 29(12) should refer to Article (27)(2), point (**e**) (and not point (d))

Article 30 – Inspections of other SoHO entities

Possibility to inspect SoHO entities that are not SoHO establishments – criteria defined – based on risk

Para 3 – consult the best practices agreed and documented by SCB

Article 31 – Provision for Joint MS Inspections

- **31(2) Criteria defined**
  - risks posed to one MS by activities in a SoHO establishment in another MS
  - Need for technical expertise not available in the MS where the SoHO Establishment is based
  - Other reasonable grounds agreed between the CAs of the 2 MS

- **31(3) Agreement between CAs in advance**
  - Scope, roles, powers and responsibilities

- **31(4) Compliance with national legislation** in the MS where the SoHO establishment is based + obligation to inform the establishment in advance except in specified circumstances

Article 32 – Specific obligations concerning inspectors

- **Qualifications** (university course or equivalent) – may exceptionally be replaced by considerable and relevant experience
- **Induction training** by the CA
  - Techniques and procedures
  - Relevant union and national inspection guidance (including SCB)
  - Authorisation systems in the MS
  - Legal framework
  - Technical aspects of SoHO activities
  - Technical guidelines
  - Organisation and functioning of national regulatory authorities in the MS
  - National health system in the MS
- **Continuous training** (for those participating in Joint Inspections – completion of EU training for inclusion on the Commission list at Article 69(5))
- Inspectors can be assisted by **technical experts**

Best practices agreed and documented by SCB

See also Recital 23

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Thank you

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