

Introduction to the EU SoHO Platform

@ SoHO oversight system : the implementation of the new EU regulation with a focus on the obligations for competent authorities

Rome, 08 April 2025

Legal basis

- REGULATION (EU) 2024/1938 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
- *Article 73*
- **Establishment, management and maintenance of the EU SoHO Platform**
- *Article 74*
- **General functionalities of the EU SoHO Platform**

Legal basis

- REGULATION (EU) 2024/1938 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

- *Article 73*

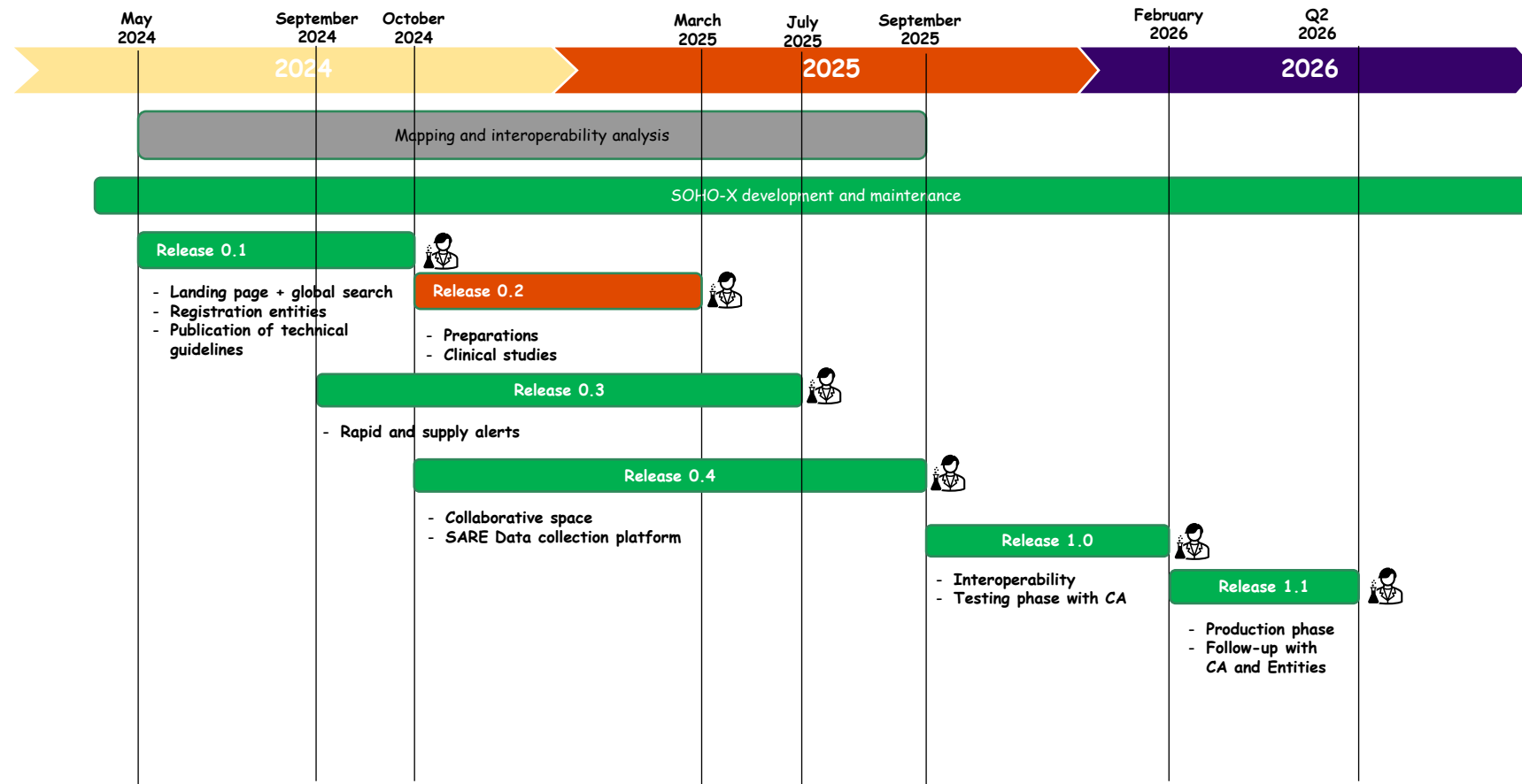
- By 7 August 2025, the Commission shall adopt **implementing acts** laying down technical specifications for the EU SoHO Platform, covering its management, maintenance, functions, including its minimal functionalities, the roles and responsibilities of each of the parties listed in paragraph 1, the retention periods for personal data and the technical and organisational measures to ensure the safety and security of personal data processed, including health data.

of the EU SoHO Platform

What's in it?



SoHO digital platform: Roadmap





Start of test phase for release.

What's in it?



EU SoHO platform **Public**

 **European Commission** | **SoHO Platform**
Substances of Human Origin

 **SEC Lookup** ▾ **Compendia** ▾ **Guidelines** ▾ **Login**

Info> For recent changes and known issues on v 0.1.79 please see the link to "Release Notes" at the bottom of the website. ✕


Home

About the EU SoHO Platform

The EU SoHO Platform is an EU-wide digital platform for the Substances of Human Origin (or SoHO for short) sector. It gathers all relevant information for stakeholders and the public at large (technical guidelines, list of SoHO entities and establishments...) and facilitates the exchange of data between SoHO entities, SoHO establishments, SoHO Competent Authorities, to ensure the quality and safety of SoHO, in compliance with personal data protection rules.


Search and view data in the EU SoHO Platform

What would you like to search for today? **Search** All ▾

 **More filters** ▴

Dashboards

SoHO Entities per Country SoHO per Category SoHO per Coding System



EU SoHO platform Logged in as SoHO Entity

The screenshot shows the EU SoHO Platform homepage. At the top, the European Commission logo and 'SoHO Platform Substances of Human Origin' are displayed. The navigation bar includes 'SoHO Entity Registration', 'SEC Lookup', 'Compendia', 'Guidelines', and a user profile dropdown for 'n00h5zrc'. A dropdown menu for 'SoHO Entity Registration' is open, showing 'Register an entity' and 'My Registrations'. A yellow info banner at the top states: 'Info> For recent changes and known issues on v 0.1.79 please see the link to "Release Notes" at the bottom of the website.' The main content area is titled 'About the EU SoHO Platform' and describes the platform's purpose. Below this is a search section titled 'Search and view data in the EU SoHO Platform' with a search bar, a 'Search' button, and a 'More filters' link. The 'Dashboards' section shows three tabs: 'SoHO Entities per Country', 'SoHO per Category', and 'SoHO per Coding System'. A map of Europe is partially visible at the bottom.

European Commission | **SoHO Platform**
Substances of Human Origin

SoHO Entity Registration ▾ SEC Lookup ▾ Compendia ▾ Guidelines ▾ n00h5zrc ▾

Register an entity
My Registrations

Info> For recent changes and known issues on v 0.1.79 please see the link to "Release Notes" at the bottom of the website.

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More filters ^

Dashboards

SoHO Entities per Country SoHO per Category SoHO per Coding System

EU SoHO platform

Logged in as SoHO Entity

Register your entity

Contact information ⓘ

SoHO Entity name *

Responsible person's name *


Administrative email address *

Administrative address ⓘ


Street

City

Post Code

 Add activity address ⓘ

Activity Address

Address details 

Street

City

Post Code

Activity details (e.g activity/department/building/floor)

Phone number *

Country *

Select

National Code ⓘ

SoHO Entity ID

SoHO Entity ID will be generated automatically

EU SoHO platform

Logged in as SoHO Entity

Declarations

I acknowledge that the SoHO Entity may be inspected pursuant to Article 28 and that it will cooperate with the relevant Competent Authority in any matter to the conduct of the SoHO supervisory activities in accordance to this Regulation *

Do you have any relevant accreditation(s) or certification(s) from an external body?

Good manufacturing practice (GMP) certification

International Standards Organisation (ISO) certification

ISO standard numbers * ISO 17025

Joint Accreditation Committee, ISCT and EBMT (JACIA)

Other certification

Do you carry out activities regulated under other Union legislation?

Authorisations

As a SoHO Entity I declare that I need authorisation

Additional information

EU SoHO platform

Logged in as SoHO Entity

SoHO Category and activities

Add a new category
Select category
-

Select activities

- ☐ SoHO donor registration
- ☐ SoHO donor history review and medical examination
- ☐ Testing
- ☐ Collection
- ☐ Processing
- ☐ Quality control
- ☐ Storage
- ☐ Release
- ☐ Distribution
- ☐ Import
- ☐ Export
- ☐ Human application

Note: Activity status will be set as "RQ - Requested" by default

Add selected category and activities

	Category	Detail	SoHO donor registration	SoHO donor history review ...	Testing	Collection	Processing	Quality control	Storage	Release	Distribution	Import	Export	Human application
	Cardiovascular, Vessels													

C: Critical NC: Not critical

EU SoHO platform

Logged in as SoHO Entity

* Toggle of Critical/Non-critical is only enabled once declaration of critical entity self-assessment is checked

I declare that we did a self-assessment about being a critical entity

☐

If you select collection as activity please fill in the SOHO establishment responsible for the release

Additional information

Do you perform some/all of your SoHO activities under an agreement with SoHO Establishment(s)?

☒ Yes ☐ No



Category/Activity 

Overseeing establishment



Select



Add

EU SoHO platform

Logged in as SoHO Entity

			ation donor	donor / rev...		ion	sing	/ control	e	e	ution		ation
	Cardiovascular, Vessels				NC			NC					
	Musculoskeletal, Bone	Post Mortem					NC		NC				
		Pre Mortem Autologous					C		NC				

C: Critical NC: Not critical

If you select collection as activity, please fill the information below


Additional information

The SoHO entity is also a SoHO establishment

☐ Yes ☒ No

Do you perform some/all of your SoHO activities under an agreement with SoHO Establishment(s)?

☐ Yes ☒ No

Category/Activity 

Overseeing establishment

Select



Add

I declare that they did a self-assessment about being a critical entity



EU SoHO platform

Logged in as SoHO Entity

Authorisations ⓘ

As a SoHO Entity, I declare that I need authorisation ○ Yes ● No

☐ SoHO Establishment
☐ SoHO Importing Establishment
☐ SoHO Preparation

Additional Information

Documents Upload ⓘ

Documents

Attachments are limited to a combined maximum size of 25MB.

Upload supporting or critical entity declaration documents here

Select document type for upload

☒ Supporting document ☐ Critical entity declaration

Choose File

No file chosen

Assign Competent

Competent Authority *

× Cancel

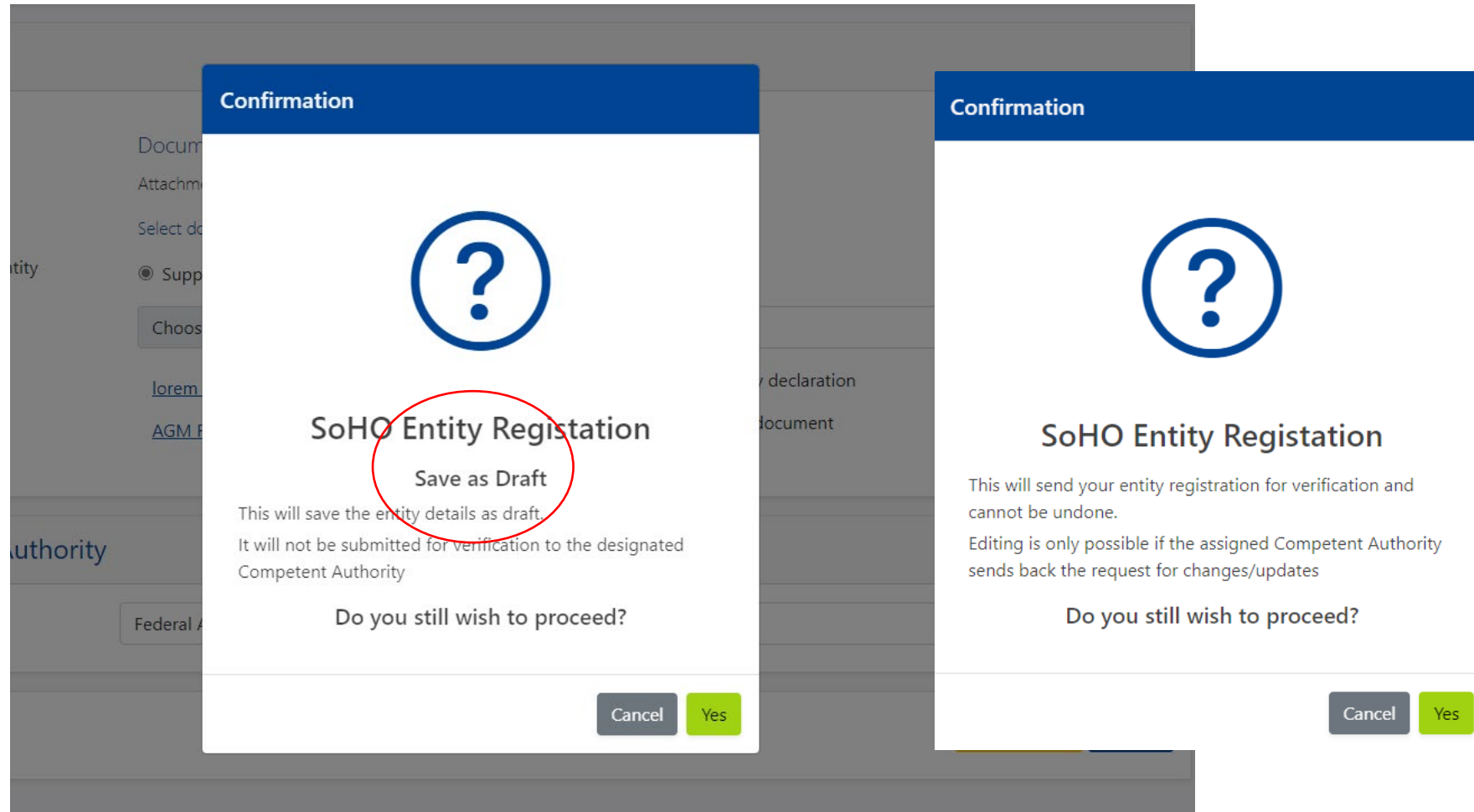
Save as draft

Submit

Appears only if there are more than one competent authority otherwise assigned by default!

EU SoHO platform


Logged in as SoHO Entity



EU SoHO platform

Logged in as SoHO Entity

Confirmation



SoHO Entity Registration

The following irregularities were found in the registration:

- **Soho Establishment qualification**
You have selected one or more of the following activity options
 - Both **PROCESSING** and **STORAGE**
 - **RELEASE**
 - **IMPORT**
 - **EXPORT**

However, you have answered "No" or did not check any of the boxes on the following options


- In Authorisation: **SoHO Establishment**
- In Authorisation: **SoHO Importing Establishment**
- In SoHO Category and Activities: **The SoHO entity is also a SoHO establishment**

Do you still wish to proceed?

Cancel

Yes

Confirmation



SoHO Entity Registration

The following irregularities were found in the registration:

- **Critical Declaration**
You have marked at least one activity as Critical in the Categories and Activities section


However, you have not uploaded any Critical entity declaration document

Do you still wish to proceed?

Cancel



Yes

EU SoHO platform Logged in as Competent Authority



European
Commission


SoHO Platform
Substances of Human Origin

 SoHO Entity Registration ▾ SEC Lookup ▾ Compendia ▾ Guidelines ▾  Massimo AMBROSIO ▾

My Registrations

Publish verified SoHO Entity

Add multiple verified SoHO entity registrations

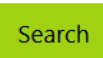
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Search and view data in the EU SoHO Platform



All ▾

 **More filters** 

Dashboards

SoHO Entities per Country SoHO per Category SoHO per Coding System

EU SoHO platform

Logged in as Competent Authority

[Home](#) > Registrations

Registrations

Pending verificationItems per page: 10Date desc

More filters

007306 - Test entity Massimo 1 Belgium 📞 +32229428452	ESTABLISHMENT	Registration date 14/10/2024	Pending Verification	Verify	▼
007300 - Test before demo Marco1 Belgium 📞 34455	ESTABLISHMENT	Registration date 14/10/2024	Verified	Edit	▼
007280 - Marco11 Belgium 📞 65767676	ESTABLISHMENT	Registration date 11/10/2024	Pending Verification	Verify	▼
007260 - Test Marco 1 - my street City, 123654 Belgium 📞 8745997	ESTABLISHMENT	Registration date 08/10/2024	Verified	Edit	▼
458965 - Marco Test BE - street Arlon, 1254 Belgium 📞 66556655		Registration date 13/06/2024	Pending Verification	Verify	▼
006468 - Banque de tissus et cellules - 100 Rue du Méridien Saint-Josse-ten-Noode, 1210 Belgium 📞 +32(0)22259111		Registration date 02/05/2016	Suspended		▼

Showing 1 to 6 of 6 entries
Total page 1

FirstPrevious1NextLast

EU SoHO platform

Logged in as Competent Authority

Declarations

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Good manufacturing practice (GMP) certification

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ISO standard numbers * ISO 9001

Joint Accreditation Committee, ISCT and EBMT (JACIA)

Other certification

Do you carry out activities regulated under other Union legislation?

Authorisations

As a SoHO Entity I declare that I need authorisation

SoHO Establishment

SoHO Importing Establishment

SoHO Preparation

Additional information

EU SoHO platform

Logged in as Competent Authority

Request supplementary information

Compose your message

Delete message text

Coassign Competent Authority

Competent Authority

Select Competent Authority

× Cancel

Remove request

Request supplementary information

Reassign request

EU SoHO platform

Logged in as SoHO Entity

Delete message text

Request

To: Mickey@disney.com From: Massimo.AMBROSIO@ec.europa.eu

2024-10-14 15:17:05.306

Please submit Establishment Authorisation

× Cancel

Save as draft

Submit

EU SoHO platform

Logged in as Competent Authority

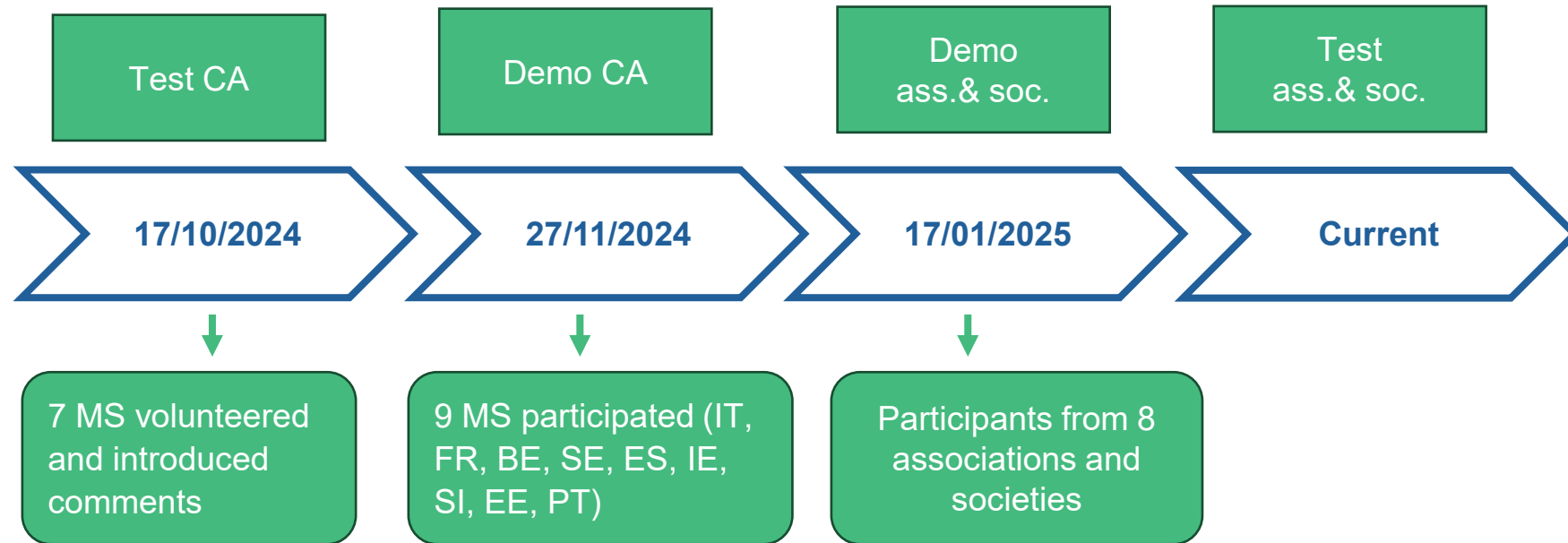
Authorisations

As a SoHO Entity I declare that I need authorisation

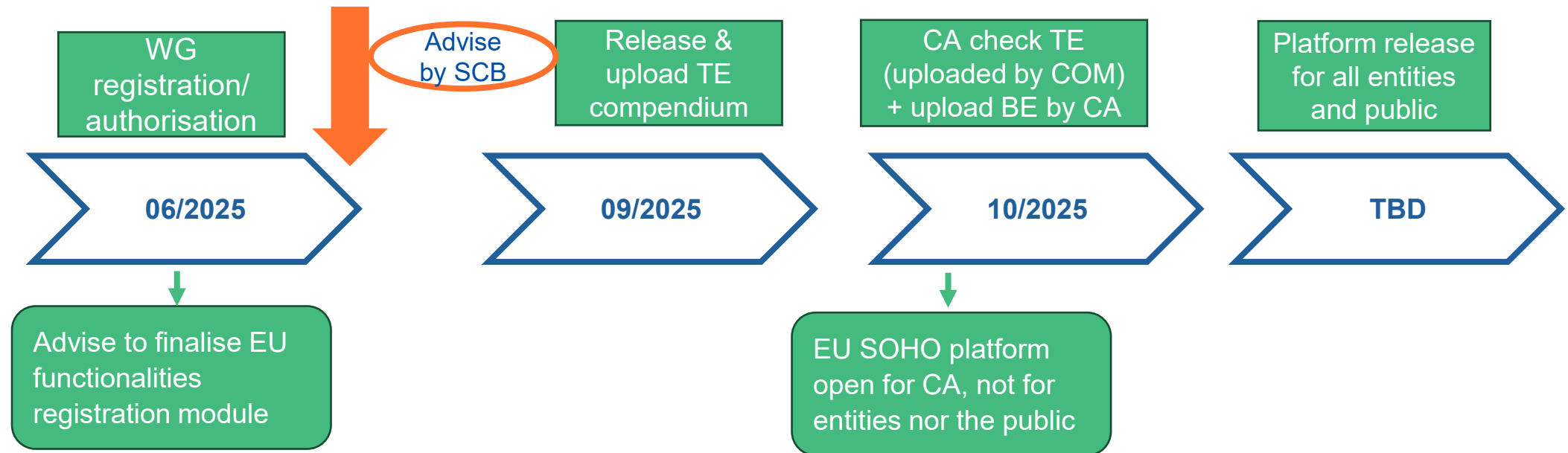
☒ Yes ☐ No

SoHO Establishment	<input checked="" type="checkbox"/>
<input type="button" value="Validate"/> Approve SoHO Establishment	<input type="radio"/> Validated <input type="radio"/> Rejected <input type="radio"/> Not under my authority
SoHO Importing Establishment	<input type="checkbox"/>
SoHO Preparation	<input type="checkbox"/>
Additional information	<input type="text"/>

Registration: status and next steps – SoHO platform (1/2)



Registration: status and next steps – SoHO platform (2/2)



National and other Competent Authorities

- Completing a task requested by the SoHO Regulation

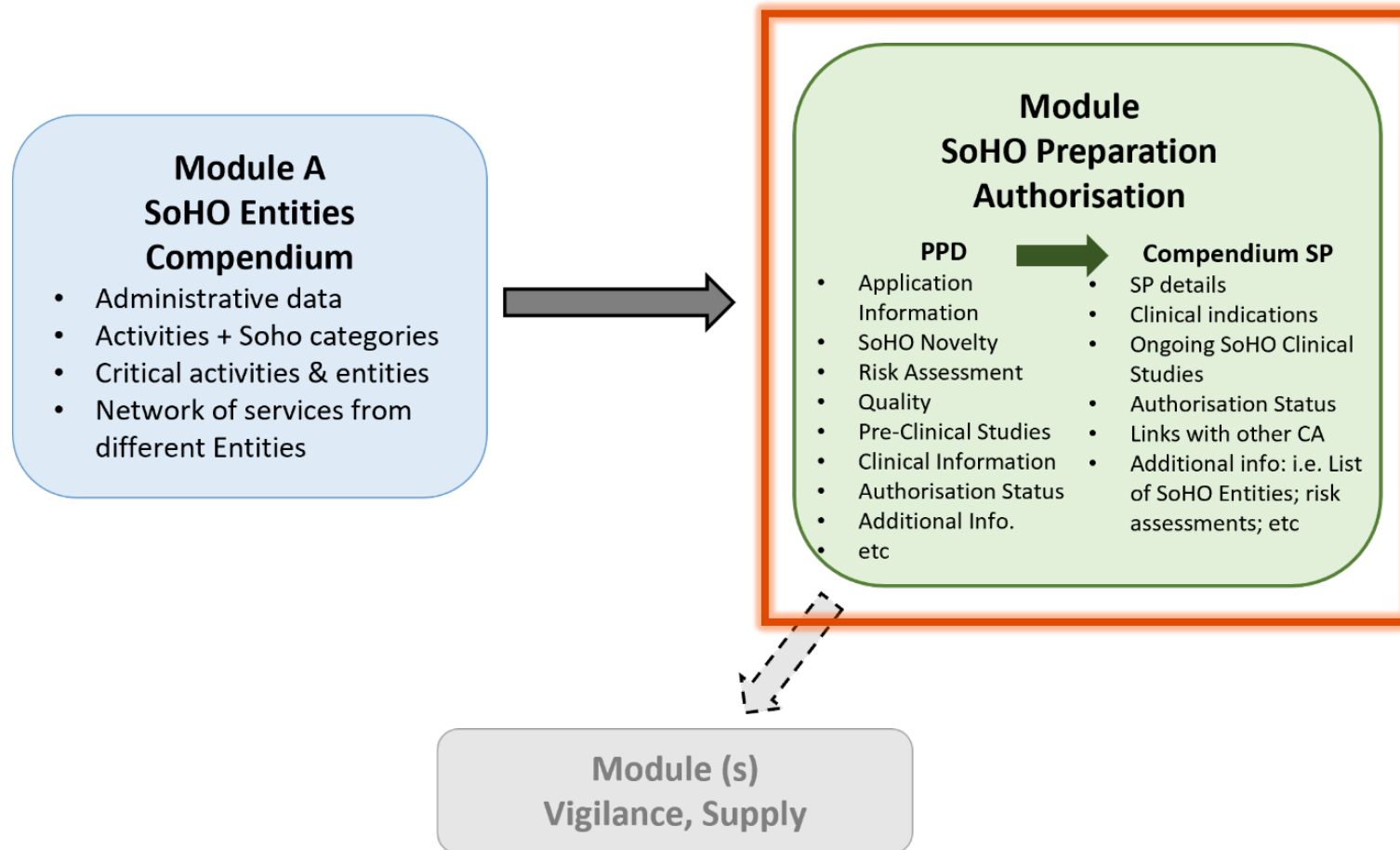


- Needed to understand future organisation of SoHO sector in MS, and to organise digital tasks...
 - E.g., data transfer on authorized tissue/SoHO establishments from EU Coding compendium to EU SoHO platform

SPA module



SPA Module – interconnectivity within SoHO Platform



SPA module - Which level of data is expected?



New SoHO Preparation Registration

SoHO Preparation Details

1. Name of the SoHO Preparation *

Enter preparation name

2. EUTC Code *

Select

3. Donor-Recipient Relationship *

Select all

- ☐ Allogeneic Related
- ☐ Allogeneic Unrelated
- ☐ Allogenic
- ☐ Autologous
- ☐ Fertility preservation
- ☐ Non Partner (MAR)
- ☐ Partner (MAR)

4. Collection

Select all

- ☐ Not Applicable
- ☐ Apheresis
- ☐ Default
- ☐ Ejaculated (MAR)
- ☐ Extracted (MAR)

5. Details of the SoHO Preparation

Select all

- ☐ Buffy coat removed
- ☐ Cryoprecipitate-depleted
- ☐ Decellularised
- ☐ Demineralized
- ☐ Irradiated (blood Components)
- ☐ Leucocyte-depleted
- ☐ Pooled
- ☐ Recovered
- ☐ Single Unit
- ☐ Washed
- ☐ Other

Additional info (Other) *

6. Additive Solution

Select

6.1 Additional Info (Additive solution)

7. Pathogen Reduction and/or Inactivation

- ☐ Not applicable
- ☐ Antibiotics
- ☐ Combined process
- ☐ ETO
- ☐ No pathogen reduction
- ☐ Not specified
- ☐ Peracetic acid
- ☐ Radiation sterilization
- ☐ Other

Additional info (Other) *

Next >



Burns

BlockL1-ND9

1. Key clinical benefits of the SoHO Preparation

2. Alternative therapies or SoHO, if any

3. Novelty Status *

Select

4. Novelty in clinical indication/target group *

☐ Yes ☒ No

4.1 Additional info *

Please detail the scientific rationale behind the proposition of a new clinical indication; and information on the earlier clinical indication

5. Pontential contra-indications

Please detail the potential contra-indications

6. Remaining level of risk (at the time of the current authorisation) *

Select

6.1 Date of Risk Assessment *

dd/mm/yyyy

6.2 Upload Risk Assessment report

Choose File No file chosen

7. Scientific evidence submitted to the Competent Authority *

☐ Internal Validation Data

☐ In vitro Studies

☐ In vivo Studies

☐ Scientific Literature / Bibliographic data

☐ Clinical Data

7.1. Scientific evidence additional info

7.2. Upload scientific evidence

Choose File No file chosen

8. Extent of Clinical Outcome data gathered for the SoHO Preparation *

Select

8.1. Upload CFupP and/or COP

Choose File No file chosen

9. Special skills or training required for application/administration of the SoHO Preparation *

Select

9.1 Details of skills and training required *

E.g. training plan for end users, number of centres involved, number of procedures required to be qualified, etc

10. Administraion form(s), concentration(s), and dosage(s) of the SoHO Preparation

11. Immediate pre-application/ implantation preparation procedures

E.g. adding solutions/ reconstitution procedures, cutting, thawing, auxiliary devices required, if any

12. Authorisation Type *

Select

12.1 Conditions for authorisation or reasons for revoking authorisation:



SPA module - how does it look like?



SPA Module – SoHO Platform

[SoHO Entity Registration](#)[SoHO Preparations](#)[SEC Lookup](#)[Compendia](#)[Guidelines](#)

[Home](#) > [List of Entities](#) > SoHO Entity Details

SoHo Entity: **BE089757**

ESTABLISHMENT

Entity Details

Name TissueVerse
EU Entity Code BE089757
Status Active
Validation Status Verified
National Code 089757
Competent Authority Federal Agency for Medicinal products and Health products

Administrative Address

Country Belgium
City Lala Land
Street Tissueverse street
Postal Code 2020

Contact Details

Person responsible John Doe

[Activities](#) [Additional Info](#) [Addresses / Uploaded documents](#) [Preparations](#)

Preparation: Lyophilized amniotic membrane

Preparation: Aortic Valve

Preparation: Frozen amniotic membrane

Preparation: Acellular Dermal Matrix

SPA Module – SoHO Platform

SoHo Entity: **BE089757**

ESTABLISHMENT

Entity Details

Name

TissueVerse

EU Entity Code

BE089757

Status

Active

Validation Status

Verified

National Code

089757

Competent Authority

Federal Agency for Medicinal products and Health products

Administrative Address

Country

Belgium

City

Lala Land

Street

Tissueverse street

Postal Code

2020

Contact Details

Person responsible

John Doe

Phone

+99 9999999

Email

Tissueverse@tissueverse.com

Back

Activities

Additional Info

Addresses / Uploaded documents

Preparations

Preparation: Lyophilized amniotic membrane

▼

Preparation: Aortic Valve

▼

Preparation: Frozen amniotic membrane

▼

Preparation: Acellular Dermal Matrix

▲

EUTC Code:

SKIN, OTHER

Status:

Pending Verification

Donor-Recipient Relationship:

✓ Allogeneic Related

Collection:

✓ Default

Details of the SoHO Preparation:

✓ Decellularised

Additional Information (Other):

<None>

Additive Solution:

No

Additional Information

<None>

Clinical Indication(s)

#	Title	Details
1	Hernias	<div></div>
2	Soft tissue disorders	<div></div>
3	Burns	<div></div>
4	Symptoms, signs or clinical findings of the musculoskeletal system	<div></div>
5	Other conditions of the genitourinary system	<div></div>

View full preparation details



SPA Module – SoHO Platform

[SoHO Entity Registration](#)[SoHO Preparations](#)[SEC Lookup](#)[Compendia](#)[Guidelines](#)[Home](#) > SoHO Preparation DetailsPreparation name: **Acellular Dermal Matrix**EUTC Code: *SKIN, OTHER*Status: **Pending Verification**Donor-Recipient Relationship: ☒ *Allogeneic Related*Collection: ☒ *Default*Details of the SoHO Preparation: ☒ *Decellularised*Additional Information (Other): *<None>*Additive Solution: *No*Additional Information (Other): *<None>*Pathogen Reduction: ☒ *Antibiotics*[Clinical Indication #1](#)[Clinical Indication #2](#)[Clinical Indication #3](#)[Clinical Indication #4](#)[Clinical Indication #5](#)[Back](#)

SoHO Preparation Authorisation

Hernias

BlockL1-DD5

Key clinical benefits of the SoHO Preparation:

<None>

Alternative therapies of SoHO, if any:

<None>

Novelty Status:

Established in EDQM Monograph, authorised before Aug 2027

Novelty in clinical indication/target group:



Additional info:

<None>

Potential contra-indications:

<None>

Remaining level of risk:

Negligible

Date of risk assessment:

Sun Jan 19 01:00:00 CET 2025

Scientific evidence submitted to the Competent Authority:

- ☒ *Internal Validation Data*
- ☒ *In vivo Studies*
- ☒ *Scientific Literature / Bibliographic data*

Additional info:

<None>

Extent of Clinical Outcome data gathered:

Serious Adverse Reactions and Events (SARE)

Details of skills and training required:

<None>

SPA – Overall planning of implementation^{Proposal}

Present

Authorisation of SoHO **Activities**,
as part of authorisation of
blood/tissue establishments
(information on SPs is not
(generally) available)

2026

Migration of information related to
existing **preparations** (SPs)
(SoHO Entities → CAs →
Platform)

Information related to novelty and
risk
(based on EDQM Monographs
and Risk Assessment)

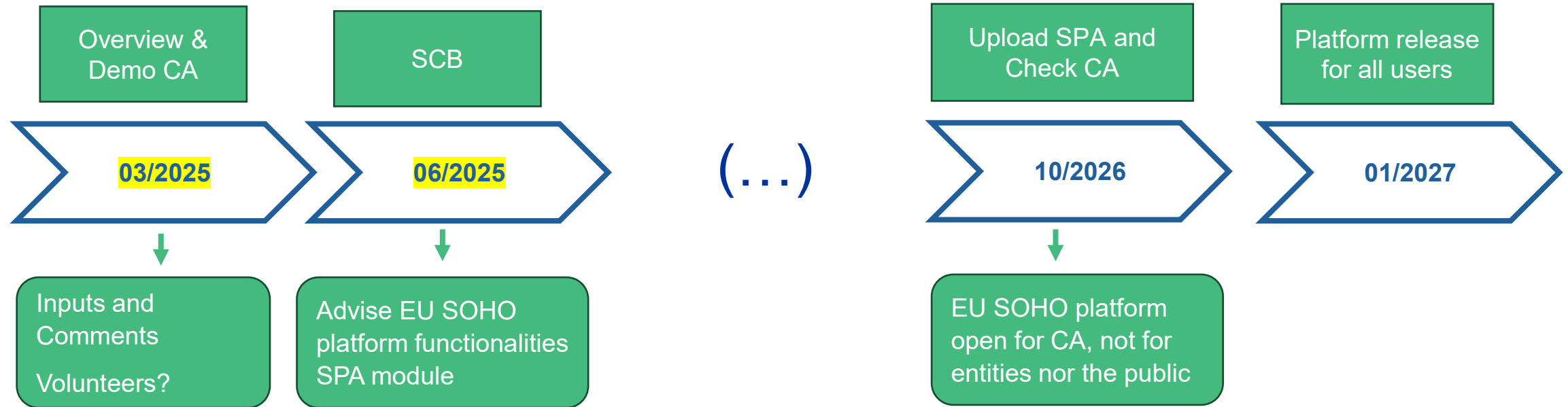
August 2027

Authorisation of SoHO **Activities**
and **Preparations**:

- PPD Template and
associated procedures (GAPP
+ GAPP Pro), validated by
SCB
- New SPs will require SPA and
data registration in the SoHO
Platform
- Information to be shared
among CAs (when applicable
and as appropriate)
- best practices documented and
published by the SCB (Art 69(1)
and 19(4))



SPA - Next Steps



What's in it?



Thank you



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