

Standard operating procedure

Title: Assignment of SME status		
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1. Purpose

To describe the procedure for assigning SME status to companies pursuant to Articles 2.1 and 4 of [Regulation \(EC\) No 2049/2005](#) of 15 December 2005, and Annex V of [Regulation \(EU\) No 2024/568](#) of 7 February 2024.

Scope

This SOP applies to the SME Office (TRS-SME) in the Regulatory Science and Innovation Task Force, the Accounting Service (A-FI-ACC) in the Finance Department (A-FI) within the Administration and Corporate Management Division (A), and the Legal Department (AF-LD) within the Advisory Functions (AF), if necessary.

2. Responsibilities

It is the responsibility of the Head of Service and Head of the Task Force to ensure that this procedure is adhered to. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

3. Changes since last revision

Update to reflect changes brought by the entry into force on 1 January 2025 of [Regulation \(EU\) 2024/568](#) on fees and charges payable to EMA.

4. Documents needed for this SOP

All templates can be found at: [X:\Templates\Others\SME\SME submissions](#)

- Template 1: Sign off sheet
- Template 2: Acknowledgment of receipt to applicant

- Template 3: Request for clarification
- Template 4: Reminder
- Template 5: Information of closure of SME file to applicant
- Template 6: Qualification of SME status – new assignment
- Template 7: Qualification of SME status – new assignment regulatory consultancy or annexed to consultancy

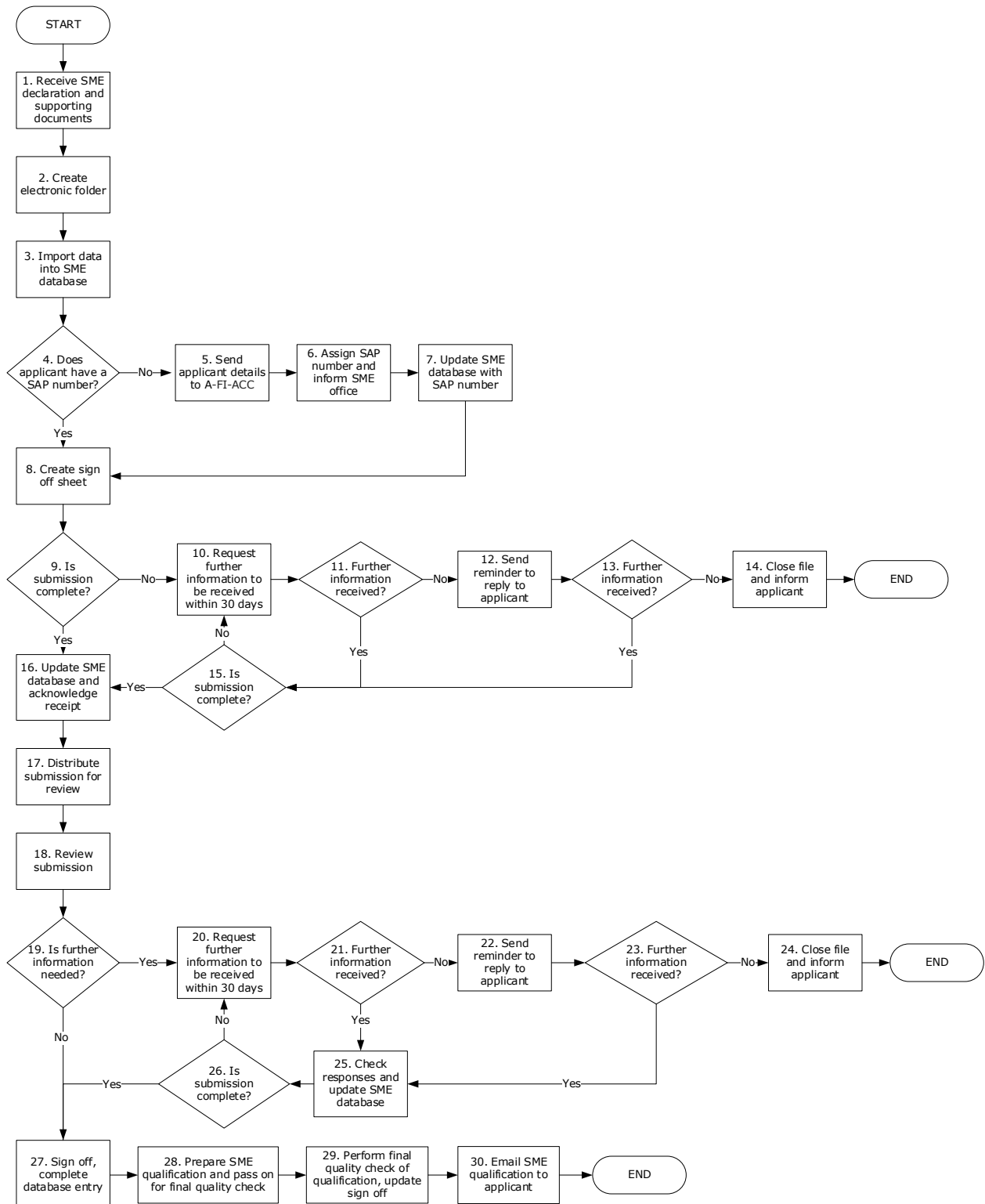
5. Related documents

- [Declaration on the qualification of an enterprise as a micro, small or medium-sized enterprise \(SME\)](#)
- [Regulation \(EC\) No 2049/2005](#)
- [Regulation \(EU\) No 2024/568](#)
- [SOP/EMA/0124 on Renewal of SME status](#)

6. Definitions

A:	Administration and Corporate Management Division
AD:	Administrator
AF:	Advisory Function
A-FI:	Finance Department
A-FI-ACC:	Accounting Service
AF-LD:	Advisory Function – Legal Department
AST:	Assistant
DREAM:	Document records electronic archive management system
EC:	European Commission
EEA:	European Economic Area
EMA:	European Medicines Agency
HSer:	Head of Service
No:	Number
SAP:	Systems, Applications & Products in Data Processing
SME:	Small- and Medium-sized Enterprise
SOP:	Standard Operating Procedure
TRS:	Regulatory Science and Innovation Task Force
TRS-SME:	Regulatory Science and Innovation Task Force – SME Office

7. Process map(s)/ flow chart(s)



8. Procedure

Step	Action	Responsibility
Start of procedure		
1	Receive SME declaration form electronically in XML format and as a signed pdf document. Check that submission includes supporting documents (latest annual accounts/annual report(s)/bona fide estimate of financial data, proof of establishment and upstream/downstream ownership). Check documents to support proof of establishment with AD in AF-LD (if necessary).	AST in TRS-SME
2	Create electronic folder for applicant in DREAM.	AST in TRS-SME
3	Import data from XML file into SME database.	AST in TRS-SME
4	If there is no SAP customer account number in the SME database, go to step 5. If SAP customer account number exists, go to step 8.	AST in TRS-SME
5	Complete the SAP form customer number and submit it to A-FI-ACC requesting a SAP customer account number to be created.	AST in TRS-SME
6	Assign SAP customer account number and inform SME Office by email.	AST in A-FI-ACC
7	Upon receipt of SAP customer account number from A-FI-ACC, update SME database.	AST in TRS-SME
8	Create sign off sheet (template 1).	AST in TRS-SME
9	If submission is complete, go to step 16. If submission is not complete, go to step 10.	AST in TRS-SME
10	Acknowledge receipt, request further information to be submitted within 30 days (template 2) and update SME database.	AST in TRS-SME
11	If further information is received, go to step 15. If further information is not received within 15 days, go to step 12.	AST in TRS-SME
12	Send reminder to reply to request for clarification (template 4) to applicant.	AST in TRS-SME
13	If further information is received, go to step 15. If further information is not received within 30 days, go to step 14.	AST in TRS-SME
14	Send email to applicant informing that the file has been closed (template 5) and update SME database.	AST in TRS-SME
15	If submission is complete, go to step 16. If submission is not complete, go to step 10.	AST in TRS-SME
16	Acknowledge receipt (template 2) and update SME database.	AST in TRS-SME
17	Send email to HSer/AD to distribute submission for review.	AST in TRS-SME
High-level review of SME declaration and supporting documentation		
18	Check consistency of information in declaration form with supporting documentation (latest audited annual accounts/annual report(s)/bone fide estimate of financial data and upstream/downstream ownership), applicant's website (if	AST/AD in TRS-SME

Step	Action	Responsibility
	applicable) and precedents/clarifications received on the SME definition (5.2.4 in DREAM). If a query arises relating to interpretation of the EC definition of an SME, liaise as applicable with AD responsible within TRS-SME to send a request for clarification to AF-LD and/or designated contact point within the EC. Update SME database.	
19	If further information is required, go to step 20. If further information is not required, go to step 27.	AST/AD in TRS-SME
20	Request further information to be submitted within 30 days (template 3) and update SME database.	AST/AD in TRS-SME
21	If further information is received, go to step 25. If further information is not received within 15 days, go to step 22.	AST/AD in TRS-SME
22	Send reminder to reply to request for further information (template 4) to applicant.	AST in TRS-SME
23	If further information is received, go to step 25. If further information is not received within 30 days, go to step 24.	AST/AD in TRS-SME
24	Send email to applicant informing that the file has been closed (template 5) and update SME database.	AST in TRS-SME
25	Check adequacy of responses and update SME database.	AST/AD in TRS-SME
26	If submission is complete, go to step 27. If submission is not complete, go to step 20.	AST/AD in TRS-SME
27	Finalise submission review (update database; sign-off sheet template 1) and inform AST as applicable.	AST/AD in TRS-SME
28	Send email for quality check of qualifications by HoSer/AD. For regulatory consultancy or companies annexed to a consultancy, attach SME qualification email (template 6).	AST in TRS-SME
Notification of SME status within 30 calendar days (excluding clarification phases between steps 10-16 and 20-25)		
29	Perform quality check of qualifications, update sign-off sheet (template 1) and inform AST.	AD/HSer/ in TRS-SME
30	Send qualification email from the database for EEA-based companies (template 6). For regulatory consultancy or companies annexed to a consultancy email SME qualification to the regulatory consultancy (template 7).	AST in TRS-SME
End of procedure		

9. Records

All documentation and correspondence are saved electronically in the appropriately labelled folder in DREAM.

New qualifications generated by the database are saved in Outlook/All Public Folders/Chrono out/Chrono SME - New qualification.

New qualifications for regulatory consultancies and annexed companies are saved in DREAM in the regulatory consultancy folder and in Outlook/All Public Folders/Chrono out/Chrono SME - New qualification.