



Standard operating procedure

Title: Assignment of SME status		
Status: PUBLIC	Document no.: SOP/EMA/0039	
Lead author	Approver	Effective date: 19-NOV-2018
Name: Cathrin Budnik	Name: Constantinos Ziogas	Review date: 18-NOV-2021
Signature: "on file"	Signature: "on file"	Supersedes: SOP/EMA/0039 (01-FEB-2017) TW 4684
Date: 26/10/2018	Date: 07/11/2018	TrackWise record no.: 5425

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 article 8 of [Regulation \(EU\) No 658/2014](#).

2. Scope

This SOP applies to the SME Office (S-CS-SME) in the Corporate Stakeholder Department (S-CS) within the Stakeholders & Communication Division (S), the Product and Application Business Support (I-BD-BUS) in the Business Data and Analytics Department (I-BD) within the Information Management Division (I), and the Legal Department (AF-LD) within the Advisory Functions (AF), if necessary.

3. Responsibilities

It is the responsibility of the Head of Service and Head of Department 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.

4. Changes since last revision

Changing from paper based review to paperless/electronic process.

5. Documents needed for this SOP

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

- Template 1: Administrative validation checklist and 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

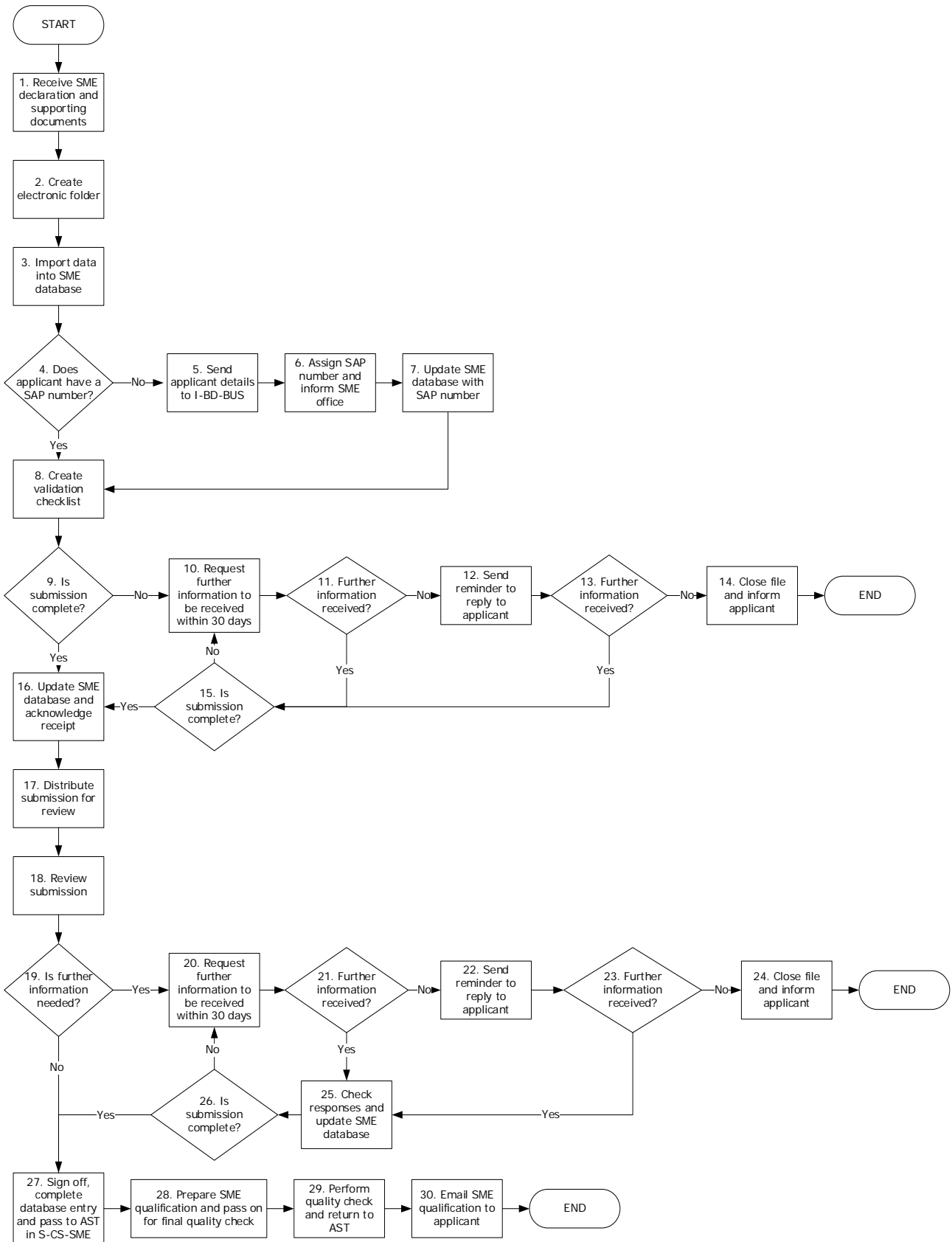
6. Related documents

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

7. Definitions

AD:	Administrator
AF:	Advisory Function
AF-LD:	Advisory Function – Legal Department
AST:	Assistant
EC:	European Commission
EMA:	European Medicines Agency
HSer:	Head of Service
I:	Information Management Division
I-BD:	Information Management Division – Business Data and Analytics Department
I-BD-BUS:	Information Management Division – Business Data and Analytics Department - Product and Application Business Support
No:	Number
S:	Stakeholders and Communication Division
S-CS:	Stakeholders and Communication – Corporate Stakeholders Department
S-CS-SME:	Stakeholders and Communication – Corporate Stakeholders Department – SME Office
SAP:	Systems, Applications & Products in Data Processing
SME:	Small- and Medium-sized Enterprise
SOP:	Standard Operating Procedure

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



9. 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 (accounts/annual report/estimates, proof of establishment and upstream/downstream ownership). Check documents to support proof of establishment with AD in AF-LD (if necessary).	AST in S-CS-SME
2	Create electronic folder for applicant in DREAM.	AST in S-CS-SME
3	Import data from XML file into SME database.	AST in S-CS-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 S-CS-SME
5	Send applicant's address and contact details to I-BD-BUS ("Financial Workflow" internal email address) requesting a SAP customer account number to be created.	AST in S-CS-SME
6	Assigns SAP customer account number and inform SME Office by email.	AST in I-BD-BUS
7	Upon receipt of SAP customer account number from I-BD-BUS update SME database.	AST in S-CS-SME
8	Create administrative validation checklist and sign off sheet (template 1), describing data submitted.	AST in S-CS-SME
9	If submission is complete, go to step 16. If submission is not complete, go to step 10.	AST in S-CS-SME
10	Acknowledge receipt and request further information to be submitted within 30 days (template 2) and update SME database.	AST in S-CS-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 S-CS-SME
12	Send reminder to reply to request for clarification (template 4) to applicant.	AST in S-CS-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 S-CS-SME
14	Send email to applicant informing that the file has now been closed (template 5) and update SME database.	AST in S-CS-SME
15	If submission is complete, go to step 16. If submission is not complete, go to step 10.	AST in S-CS-SME
16	Acknowledge receipt (template 2) and update SME database.	AST in S-CS-SME
17	Send email to Head of Service/AD to distribute submission for review.	AST in S-CS-SME
High-level review of SME declaration and supporting documentation		
18	Check consistency of information in declaration form with	AD in S-CS-SME

Step	Action	Responsibility
	supporting documentation (latest audited annual accounts/ annual report/estimates and upstream/downstream ownership), applicant's website (if applicable) and precedents/clarifications received on the SME definition (5.2.4 in DREAM). If a query arises relating to interpretation of latest EC definition of an SME, liaise with AD responsible within the office 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.	AD in S-CS-SME
20	Request further information to be submitted within 30 days (template 3) and update SME database.	AD in S-CS-SME
21	If further information is received, go to step 25. If further information is not received within 15 days, go to step 22.	AD in S-CS-SME
22	Send reminder to reply to request for further information (template 4) to applicant.	AST in S-CS-SME
23	If further information is received, go to step 25. If further information is not received within 30 days, go to step 24.	AD in S-CS-SME
24	Send email to applicant informing that the file has now been closed (template 5) and update SME database.	AST in S-CS-SME
25	Check adequacy of responses and update SME database.	AD in S-CS-SME
26	If submission is complete, go to step 27. If submission is not complete, go to step 20.	AD in S-CS-SME
27	Finalise submission (template 1) and inform AST.	AD in S-CS-SME
Notification of SME status within 30 calendar days (excluding clarification phase between steps 10-16 and 20-25)		
28	Update SME database and prepare SME qualification email (template 6 or template 7 for regulatory consultancy or companies annexed to a consultancy) and pass on for final quality check.	AST in S-CS-SME
29	Perform quality check of qualification and return to AST.	HoSer/AD in S-CS-SME
30	Email SME qualification to applicant.	AST in S-CS-SME
End of procedure		

10. Records

All documentation and correspondence is required to be saved electronically in the appropriately labelled folder in DREAM throughout the procedure.