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Information Management Division

OMS web user manual

Version 1.0

An agency of the European Union

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1. Purpose of this document

OMS (Organisation Management System) is part of the centralised EU master data service covering **S**ubstance, **P**roduct, **O**rganisation and **R**eferential (SPOR) in relation to medicines. Each of these domains is accessible through the common SPOR web portal as described below.

OMS implements Master Data Management services around registration and maintenance of organisation data and the provision of an organisation dictionary via a web user interface (UI) and an Application Programming Interface (API). The content of the organisation dictionary will be expanded incrementally. Examples of organisation data include: Marketing Authorisation Holders (MAHs), Marketing Authorisation Applicants (MAAs), Sponsors and Manufacturers. A new centralised organisation registration process is put in place as part of the OMS solution. The implementation of structured organisation data with unique IDs will also support the implementation of ISO IDMP standards such as the ISO 11615 for medicinal product identification and ISO 11238 for substance identification. Although these standards apply to human medicinal product only the SPOR services will also support veterinary regulatory activities.

This manual gives step-by-step instructions how to use the OMS web interface in order to search the organisation dictionary, view available data, request new records and update current records.

This manual does not describe the EMA internal data and process flows.

2. Web portal user roles

Refer to 'SPOR User Registration' document on the OMS web page, in the "view documents" section:

http://spor.ema.europa.eu/omswi/#/viewDocuments

3. Definitions of OMS data entities

Entity	Description
Organisation	Represents an organisation as a legal entity (e.g. organisation name). Organisations are country-specific. All locations under one organisation must be located in the same country. For the purpose of OMS, global companies are split per country even if they have the same name. Assignment of organisation IDs follows these principles.
Location	Represents a physical location (address) within an organisation. A location can only be associated with a single parent organisation at any one time. Each active organisation must have at least one active location associated with it. An address can be present in multiple locations. Each location will have a unique location ID. This location ID is maintained when the location is moved from one organisation to another organisation.

For more information about the data supported by the OMS services, refer to 'Data Quality standards in OMS' document on the OMS view documents page:
(http://spor.ema.europa.eu/omswi/#/viewDocuments)

4. Access to SPOR services

4.1. SPOR web landing area and log in to OMS

Users can access SPOR services directly through the URL for SPOR,

 http://spor.ema.europa.eu/sporwi/

Links to referentials (RMS), organisations (OMS), products (PMS; disabled until PMS goes live) and substances (SMS; disabled until SMS goes live) landing pages are available on the SPOR top menu bar.

There is also a help tab which contains general help document "About SPOR".

Figure 1. SPOR web landing page
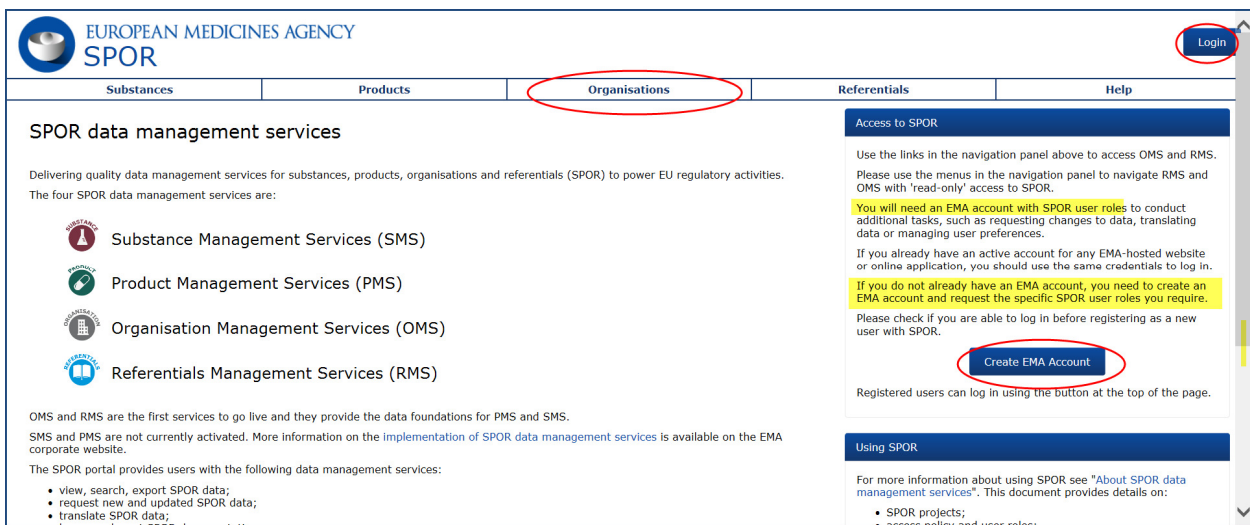
This OMS SPOR user manual is accessible in the Organisation section, under the tab "documents" (see below).

Guest users can accesses the publicly available information on the SPOR Portal Website without logging in.

SPOR users will need to be registered to use additional functionality on the SPOR portal.

Registered users who already have an EMA account (for Eudralink, EudraCT Secure, IT Service Desk portal (JIRA), MMSe, MMD, EVDAS, EudraPortal, EudraGMP, Paediatrics, BI Dashboard, EUTCT, CorpGXP, EPITT or PSUR as examples), can just click on the log in button on the top right hand corner of the SPOR landing page to log into the SPOR portal. They will be logged in as unaffiliated users.

Figure 2. OMS SPOR log in page for registered users

Registered users who wish to request SPOR user roles need to log in through the IAM (IIQ) portal under "create EMA account" as described below and log in with their EMA account username and password. They should not register again.

User registration and access to SPOR user roles is managed through the IAM identity and access management tool IdentityIQ (IIQ). The link to the IAM (IIQ) system is available on the SPOR homepage as highlighted in *fig. 1* – click on "create EMA account". The same link is also available on the OMS home page as highlighted in *fig. 3* below.

Figure 3. Create EMA account or request SPOR roles
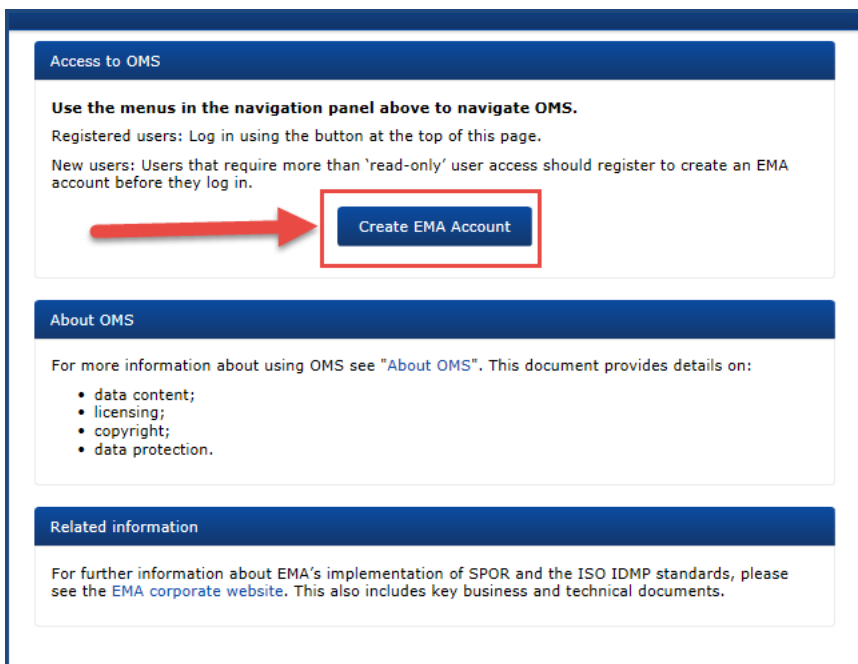
☞ *For the registration process and access rights requests please go to SPOR user registration manual on the OMS home page*
http://spor.ema.europa.eu/omswi/#/viewDocuments

Of note, there is one single registration process for all SPOR domains, i.e. by registering for one domain (e.g. OMS), the user will automatically have access to the other domains (e.g. RMS). The RMS specific SPOR user roles need to be requested in the same way as any other SPOR user roles.

5. New user registration for SPOR access

Please refer to 'SPOR User Registration Manual' on the OMS view documents page here:

http://spor-test.ema.europa.eu/omswi/#/viewDocuments

6. OMS services

6.1. OMS web landing area – before log in

To access the OMS landing page, the user must select the OMS tab on the SPOR top menu (see *fig. 1*). Before logging in, users can view OMS documentation, search for organisations/locations data and view it on the screen. To export any organisation dictionary content, the user needs to be logged in.

The log/registration screen can be accessed through 'Create EMA Account' box from the SPOR main landing page (see *fig. 1*) and from the OMS home page (see *fig.* 4).

Within the OMS domain, the available menu options are (see *fig. 4*)

- SPOR Home - opens the SPOR homepage. The same page opens by clicking on the EMA logo
- Organisations – opens the organisation dictionary search page
- Documents – view

Figure 4. OMS web landing area with log in, create EMA account and access to organisation dictionary

6.2. View help

The help menu link provides access to the 'About OMS' document. This document is available for guest users, i.e. without logging in.

The guidance documents related to OMS are accessible once the user selects the OMS menu option as in *fig. 4*.

6.3. View documents

There are two categories of supporting documents published on the OMS web portal, general and technical. When selected, each of them opens in a new tab.

The 'General' tab includes a list of business documents pertaining to the OMS solution. From data quality standards, change request documentation requirements to OMS operating model and process related documentation, including this OMS user manual. it also includes instruction on user registration and requesting SPOR roles.

The 'Technical' tab provides access to more technical documentation such as the SPOR API specification or the OMS data model.

All documents are downloadable for any user (registered or not).

Figure 5. OMS – view documents
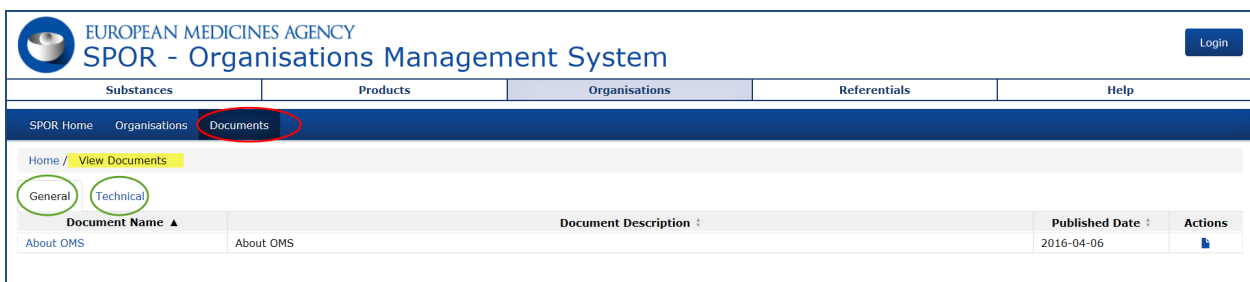
7. Search, view and export

To search and view organisations and locations, the user does not have to be logged in the OMS (guest user).

To export organisation and location data, search results or list of change requests sent in the past the user **does** need to be logged in.

7.1. Organisation and location search

This functionality allows the user to search for the organisations and locations published in OMS. Subject to permissions, they may then choose to view organisation details for an organisation returned in the search results, add a location to an organisation returned in the search results, request a change to an organisation and/or location returned in the search results, create a request to add a new organisation or export the details of the organisations in their result list.

The search is based on exact character matching. This applies to all search fields e.g. if searching for Székesfehérvár, special characters "é" and "á" will need to be used.

Once the search criteria are inserted, clicking on "search" will run the query.

Default sort order is organisation ID, organisation name and country.

All columns are sortable.

There can be more than one page of results, up to the limit 200 rows in the result. If more than 200 rows meet the search criteria, the system will throw an error message.

Figure 6. Search start

Search organisations:

Organisation-based search:

☞ ***Please note that organisations are country-specific as described in section 3.***

- Criteria entered in "Organisation Name" will be searched against all the different name fields (Organisation Name, Acronym, Translations) and against all historic version of those names

- The user enters the name of the organisation (or part of the name) that they wish to search for

- The search results include all of the locations that are associated to organisations that match the entered organisation name. For each returned location the name and ID of the parent organisation is shown

- In order to get more refined results, the user can also use "country" as a selection criterion – type in a value in the country search field. Please note the country search field covers "modified since" and "status" fields while open and collapses once a selection is made

Figure 7. Country selection
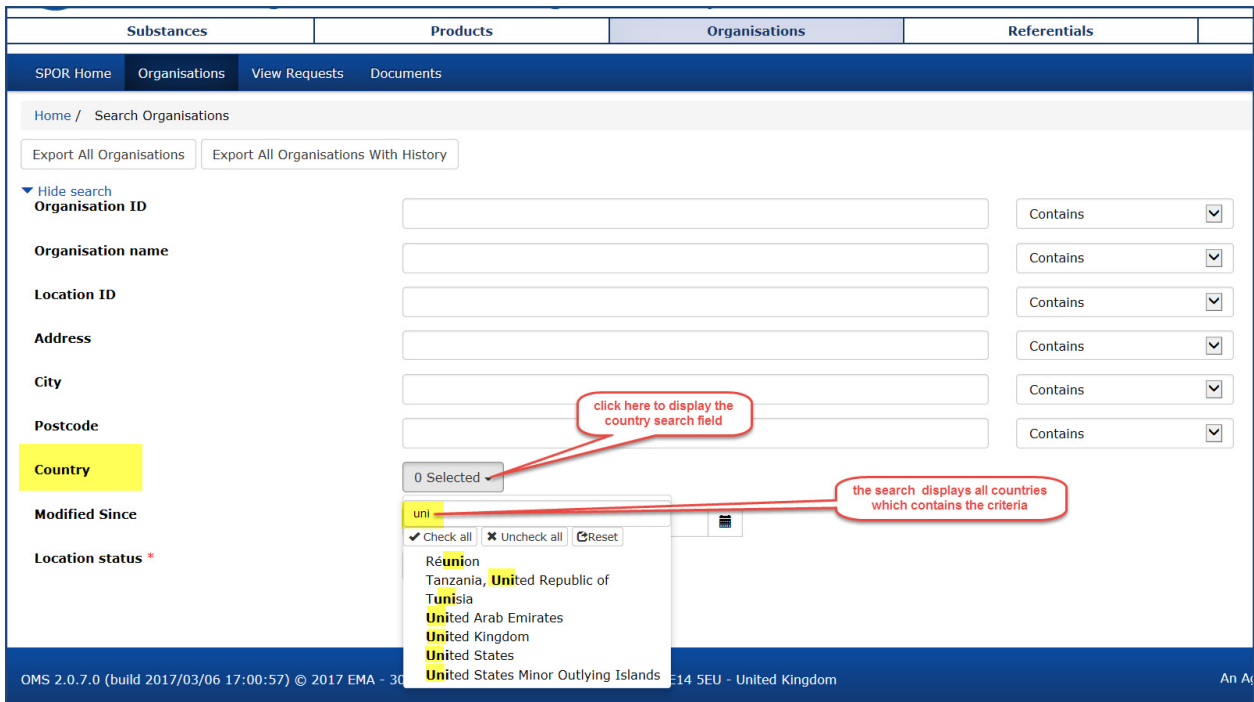
- The "modified since" and "status" fields are related to location entity and not the organisation

- Organisation ID based search will provide the organisation containing that ID. The search result will list all the locations linked to that organisation and with the organisation data repeated in each row

- The default search mode is "contains" for all fields; this can be changed to "begins with"

- The search is case insensitive

- Please note that fuzzy search for special characters is to be implemented in a future release (i.e. if searching for Grünenthal, special character "ü" needs to be used as the system is currently not able to find this name by searching for "Grunenthal")

- Country and Location status fields allow multiple selection. Location status is the only mandatory field in the search.

- One or more criteria (in addition to location status which has a default value that can be changed) must be selected/entered before choosing "Search"

- The user can choose if to display 20, 50 or 100 rows in the search results. The default sort order is the organisation ID, name and country. The result list is sortable by all columns apart from "location ID" and "modified since".

- There can be more than one page of results – see *fig. 8*

Figure 8. Search results – selection of 20, 50 or 100 search results

- Search results are limited to 200 results. If the search was to return more than 200 results, the user will see an error message informing that the search criteria should be further refined.

- Click on "search"

- Search criteria are automatically collapsed to make more space for the search results. It can be expanded by clicking on 'show search'.

Figure 9. Search results with the collapsed "show search" button

Click on "show search" and the search criteria panel appears above the search results

Figure 10. Search criterial expanded above the search results

The search form can be cleared by clicking on "reset"

Figure 11. Reset the search criteria

Location based search:

- The user enters location level search criteria (e.g. address, Location ID). The search results include all locations that match the entered search criteria. For each returned location the name and ID of the parent organisation is shown.

- Criteria entered in "Location ID" will only be searched against Location ID, although other IDs held (e.g. EVcode) will be included in the organisation detailed data display and export

Combination search:

- The user enters both organisation level and location level search criteria. The search results include locations where the location data matches the location level search criteria, and its parent organisation matches the organisation level search criteria. For each returned location the name and ID of the parent organisation is also shown.

Alternative search results:

- no results found
- minimum search criteria not entered, please enter minimum search criteria
- too many results returned, please refine your search

Further actions are possible from the results screen:
- Click on the address link – shows organisation and location details
- + icon – request to add a location for this organisation => triggers a change request
- Pencil icon – request change to this organisation and/or location => triggers a change request
- Magnifying glass icon – view organisation and location details
- Request new organisation
- In case the pencil icon is greyed out, the location record is inactive and cannot be changed. This does not mean that the organisation is inactive too. The organisation status can be seen on the organisation and locations details page.

Figure 12. Search results and further actions

7.2. View organisation location

The user is able to view the details of a particular organisation that they have selected from the results of an organisation search.

Clicking on the address or on the magnifying glass displays organisation location details.

Figure 13. View organisation and location details and take further actions

Organisation and Location details
- The default language is English
- A drop-down is enabled if the location address details are also stored in a different language

Figure 14. Drop-down list for an address in different language from English

Organisation Details

Organisation ID:	ORG-100003914
Organisation Name:	Bulgarian Drug Agency
Alternative Name:	BG - Българската агенция по лекарствата ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА
Acronym:	BDA
Status:	ACTIVE
Organisation Type:	Regulatory Authority EEA National Competent authority

Location Details

Location ID:	LOC-100000007
Address:	BG ⌄ Ул.дамян Груев 8 София София 1303 Bulgaria
GPS Location:	42.69896, 23.30993
Location Email:	bda@bda.bg
Location Phone:	+359 28903555
Last Modified Date:	2017-05-25T13:33:03
Last Modified By:	▮▮▮▮▮▮
Status:	ACTIVE

- If location status and Organisation status are both inactive, the "request change" button is disabled as it is not possible to request a change.
- If the location status is inactive but the organisation status is active, the 'request change' button should be active in order to request a change to the organisation data only.
- Organisation type refers to the categorisation of organisations in OMS. To see the full list of organisation categories with definitions, refer to the 'Definitions of OMS Controlled Vocabularies' document in the OMS general documents page (http://spor.ema.europa.eu/omswi/#/viewDocuments)

Further actions are possible from the "view organisation location" screen:

- Request new organisation
- Add a location for this organisation
- Request change to this organisation and/or location
- Export organisation and location details

- Export organisation and location details with history

Figure 15. Further action

7.3. Export all organisations

The user can export the complete organisation dictionary from the system in csv format, after logging in. The functionality is available under "search organisation" tab. The export of the complete dictionary can only be performed before starting any search or after clicking "reset".

The content of the OMS dictionary can be exported as data without history (current version of oms organisations/locations only) or with history (current as well as previous versions of OMS organisations/locations).

In order to display exported organisation data correctly including all special characters, the file needs to be downloaded and opened as per the instructions below.

Figure 16. Export all organisations

In Google Chrome (version 58.0 minimum), the file is dowloaded to the 'downloads' folder from where the user can move the file to another drive. Click on the downloads file in the botton left corner; the location of the file on your computer appears (see *fig. 7*)

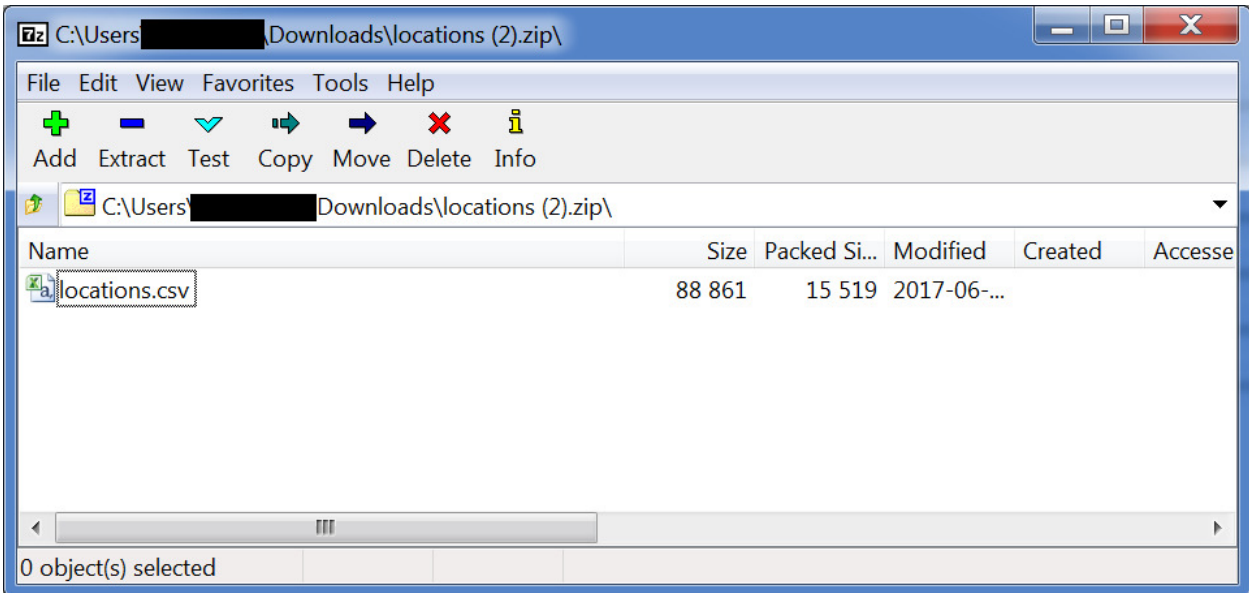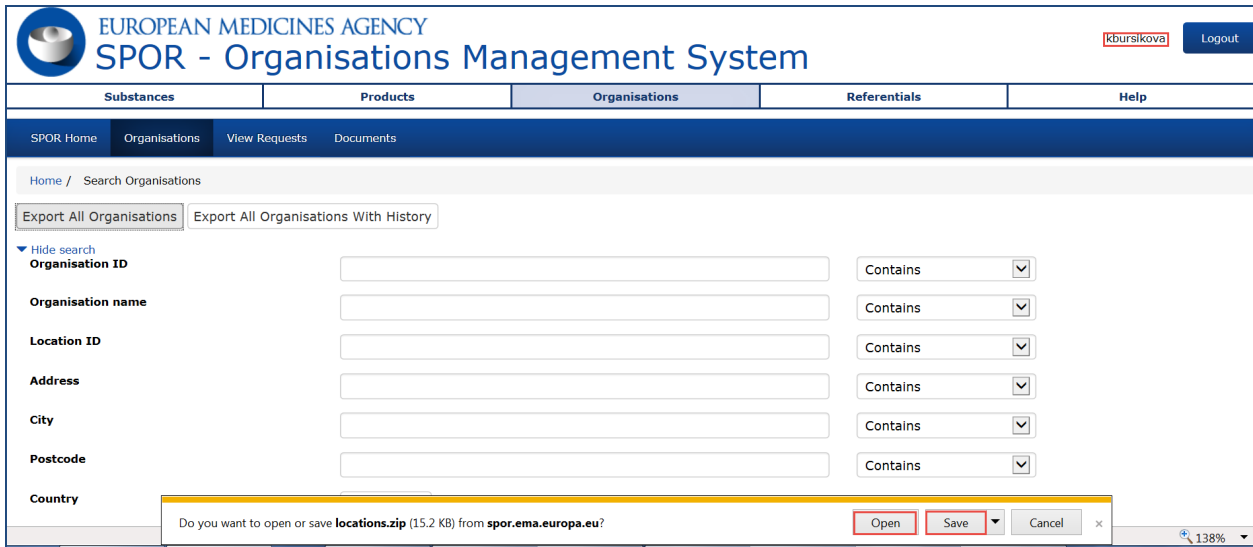**Figure 17.** Export all organisations – Google Chrome - dowloads folder
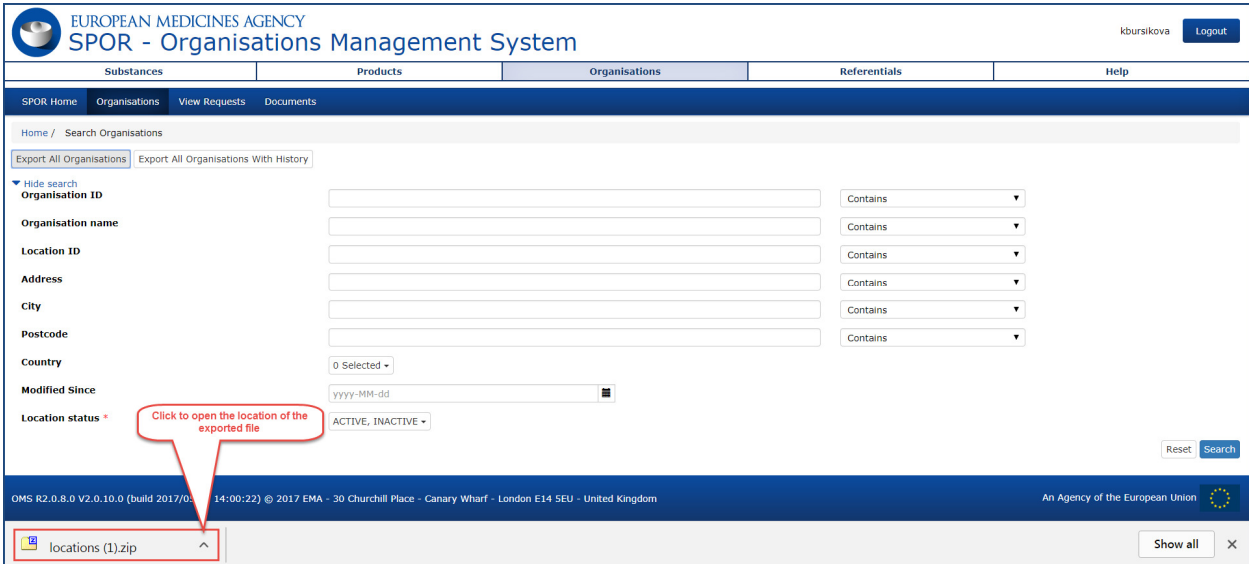
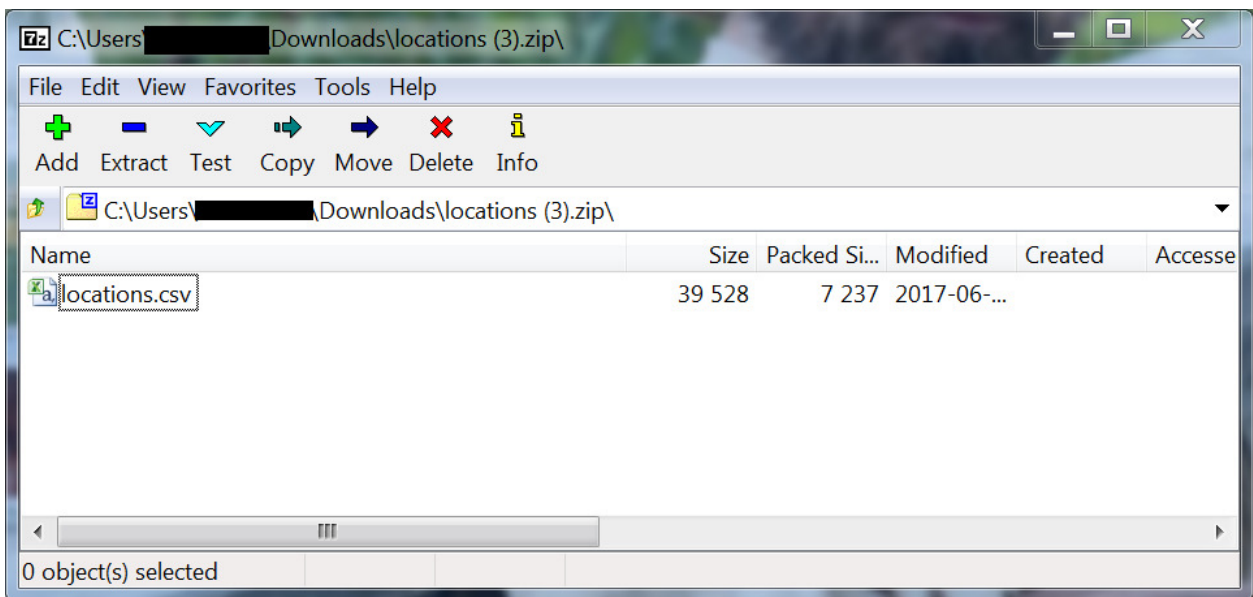**Figure 18.** Open the downloads folder – csv. file

In Internet Explorer (IE version 11 minimum), a pop-up window gives the user the option to either open or save the file as shown in *fig. 7*:

Figure 19. Export all organisations – Internet Explorer – pop-up window to open or save

Open the file. The location dowloads folder appears.

Figure 20. Open the downloads folder – csv. file

The next steps are the same both for Google Chrome and the Internet Explorer.

- <u>Open</u> the document and save it locally (e.g. on your desktop or an additional drive) – you cannot save it from the screen above

- Close the document

- Open a new clean Excel file

- Go to Data tab in Excel and click on "From Text"

Figure 21. Data tab in Excel
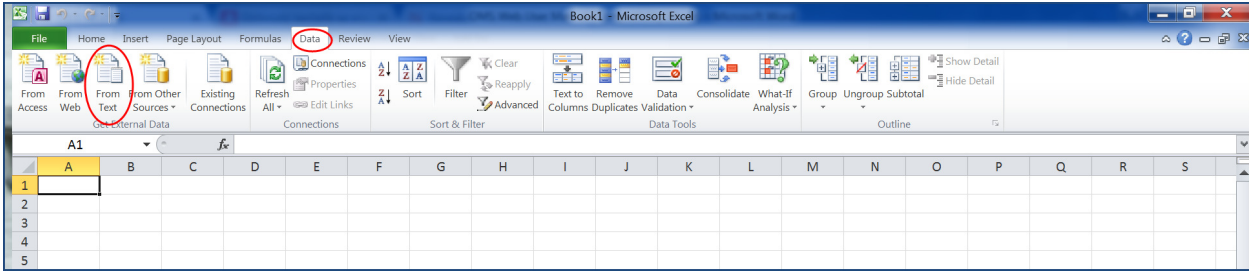
A pop-up window appears

- Select the location of the file you saved previously and open it

Figure 22. Location of the saved file
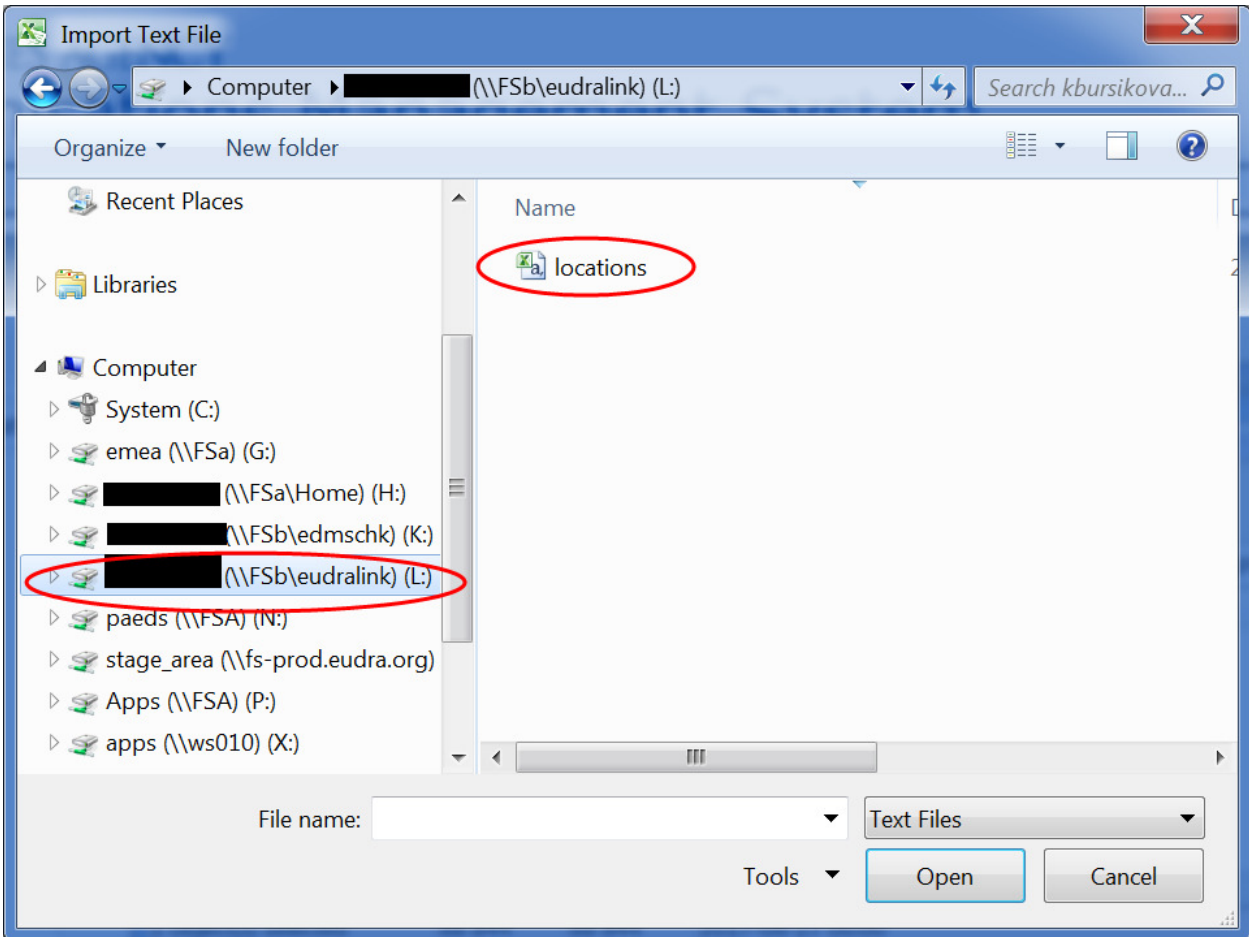
The following options are displayed:

- Select "Delimited" as file type

- Select "Unicode (UTF-8)" as file origin.

- Select Next

Figure 23. Import wizard to select file parameters
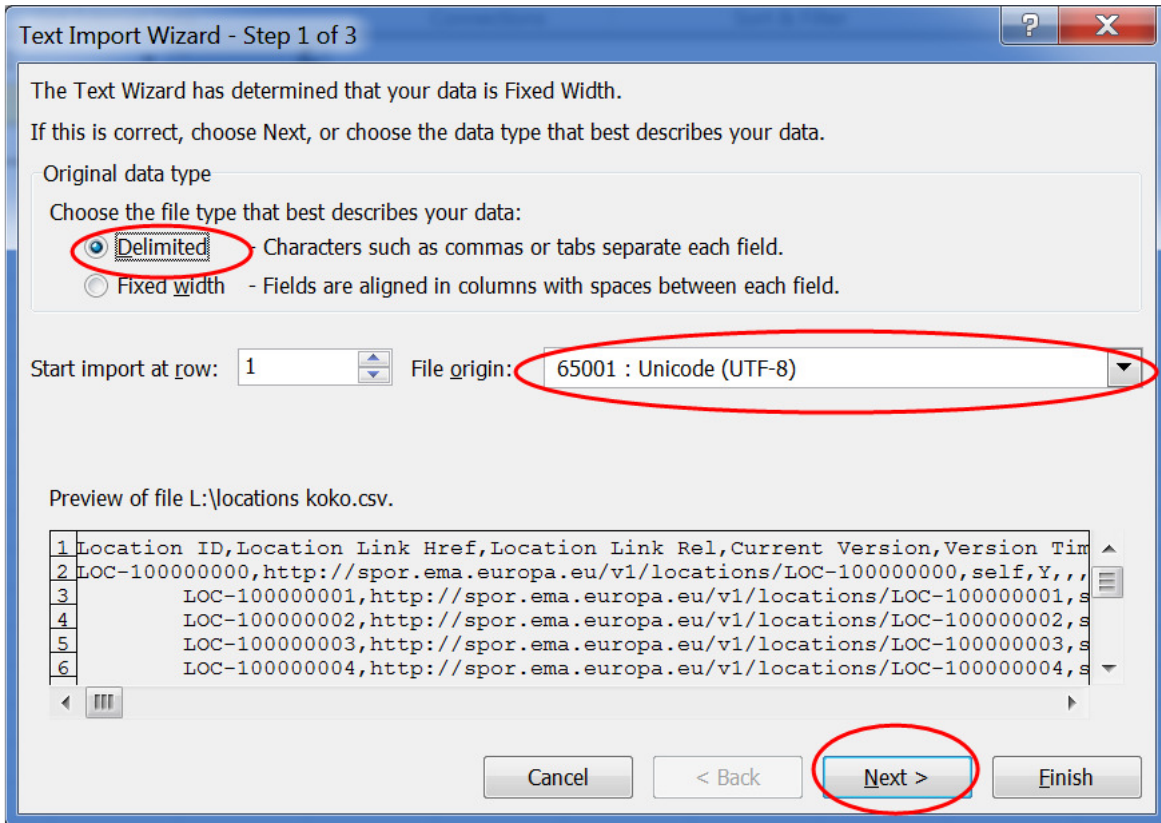
For Delimiters:

- Select Tab, Semicolon, Comma
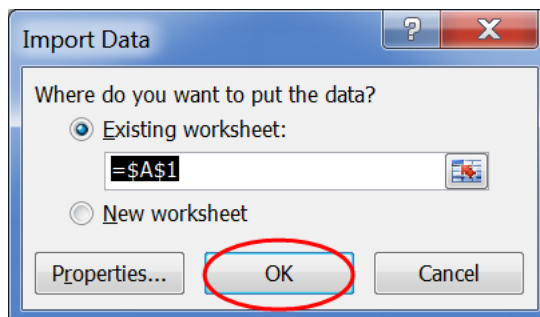
- Select Next

Figure 24. Set the delimiters
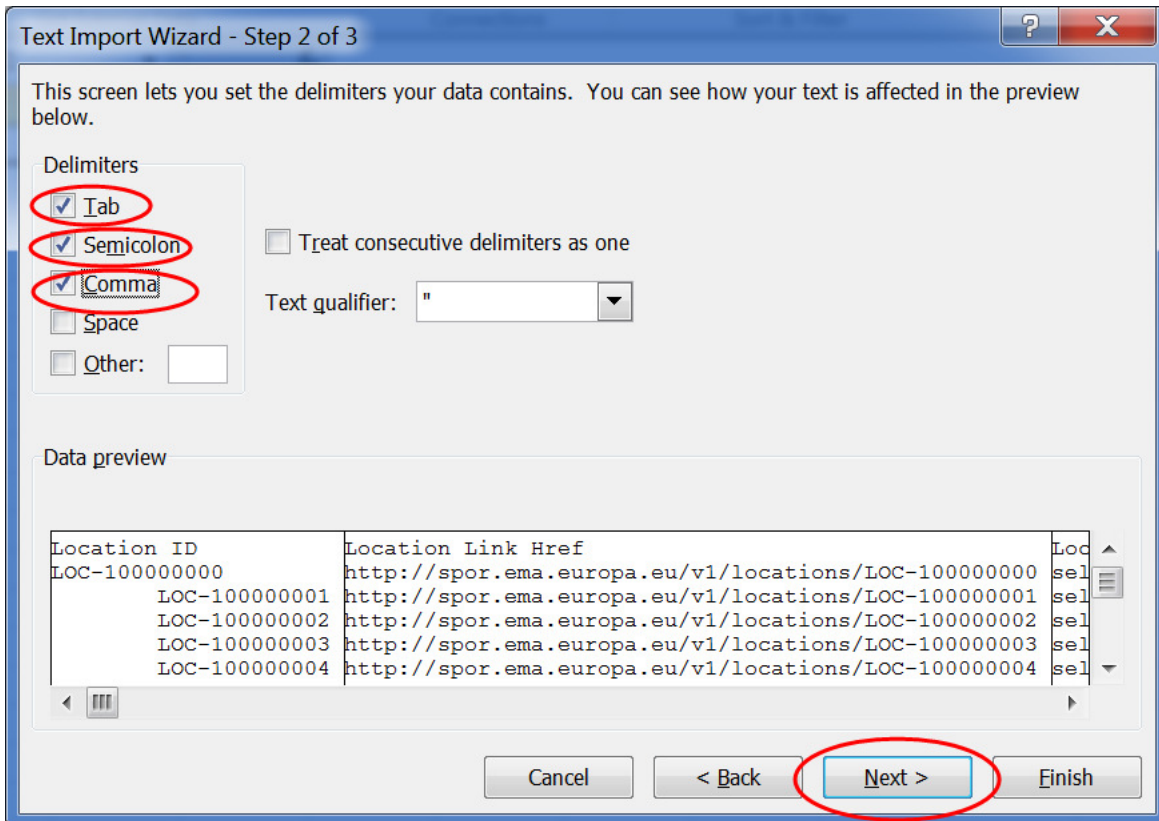
- Select Finish

Figure 25. Finish the file import
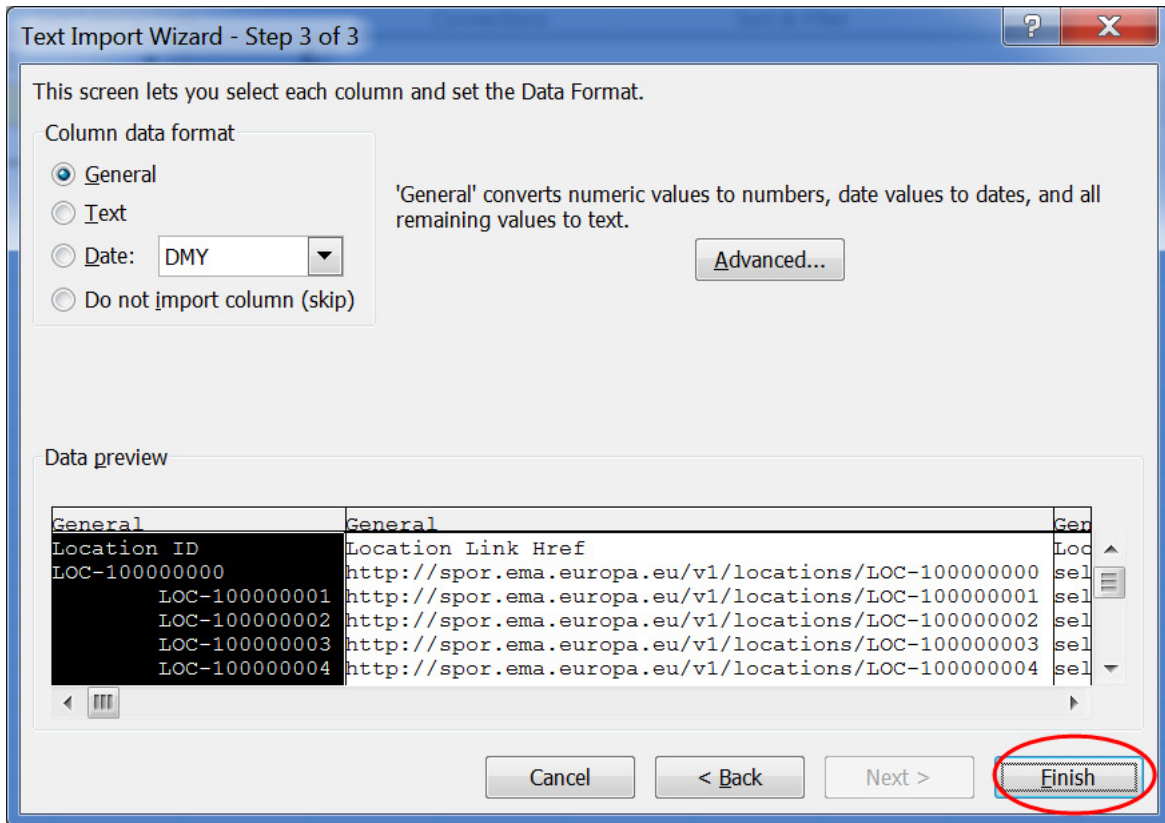
- Select OK

Figure 26. Location of the data

The file opens in the correct format, including special characters

Figure 27. Search results exported including special characters (examples highlighted)

	AE	AF	AG	AH
1	Address GPS Location	Address Language	Address Line 1	Address Line 2
2	48.25147, 16.48305	EN¦DE¦DE¦DE	Spargelfeldstrase 191¦Spargelfeldstraße 191¦Spargelfeldstraße 191¦Spargelfeldstraße 191	Vienna,donaustadt¦¦¦
3	47.075627, 15.450706	EN¦DE¦DE¦DE¦DE	Beethovenstrase 6-8¦Beethovenstraße 6¦Beethovenstraße 6¦Beethovenstraße 6-8¦Beethovenstr	Graz,03.Bez.:Geidorf¦¦¦¦
4	48.076881, 16.303951	EN¦DE¦DE	Robert Koch-Gasse 17¦Robert Koch-Gasse 17¦Robert Koch-Gasse 17	Modling¦¦
5	48.209504, 16.318259	EN¦DE	Possingergasse 38¦Possingergasse 38	Vienna,ottakring¦
6	48.234094, 16.384692	EN¦DE¦DE	Traisengasse 5¦Traisengasse 5¦Traisengasse 9	Vienna,Brigittenau¦¦
7	47.075964, 15.449859	EN¦DE¦DE	Zinzendorfgasse 27/1¦Betriebsstatte Graz¦Zinzendorfgasse 27/1	Graz,03.bez.:geidorf¦Zinzendorfgasse 27/1¦
8	50.83632, 4.33411	EN¦FR¦FR¦FR¦FR	Place Victor Horta 40¦Place Victor Horta 2¦Eurostation Gebouw¦Eurostation Blok 2¦Place Victor H	Eurostation 2¦¦Place Victor Horta/40/place V
9	42.69896, 23.30993	EN¦BG¦BG	Ul. Damyan Gruev 8¦Ул.дамян Груев 8¦Ул.дамян Груев 8	¦¦
10	45.83537, 15.97786	EN¦HR¦HR¦HR	Ksaverska Cesta 4¦Ksaverska Cesta 4¦Ksaverska Cesta 4¦Ksaverska Cesta 4	¦¦¦
11	55.661380, 12.569610	EN	Axel Heides Gade 1	
12	58.36593, 26.69561	EN	Nooruse 1	
13	60.20324, 24.89936	EN¦FI¦FI	Mannerheimintie 103b¦Mannerheimintie 103b¦Mannerheimintie 103b	¦¦
14	62.88997, 27.62966	EN¦FI¦FI	Microkatu 1¦Microkatu 1¦Microkatu 1	¦¦
15		EN	P.O. Box 55	
16	60.44507, 22.26149	EN¦FI¦FI	Itsenaisyydenaukio 2¦Itsenäisyydenaukio 2¦Itsenäisyydenaukio 2	¦¦
17	45.72664, 4.83084	EN¦FR¦FR	321 Avenue Jean Jaures¦321 Avenue Jean Jaures¦Site De Lyon	¦321 Avenue Jean Jaures
18	43.65251, 3.94899	EN¦FR¦FR	635 Rue De La Garenne¦635 Rue De La Garenne¦635 Rue De La Garenne	Cs 60007¦¦Cs 60007
19	48.93993, 2.35547	EN¦FR¦FR	143 - 147 Boulevard Anatole France¦143 Boulevard Anatole France¦143 Boulevard Anatole Franc	¦¦
20	48.804278, 2.489059	EN¦FR¦FR	7 Avenue Des Arts¦7 Avenue Des Arts¦7 Avenue Des Arts	¦¦
21		EN¦FR	105 Route Des Chappes¦105 Route Des Chappes	Cs 20111 Biot¦Cs 20111 Biot
22	64.130729, -21.765277	EN	Vinlandsleid 14	

Sheet1 / Sheet2 / Sheet3

7.4. Export search results

Search results can be also exported.

The user can export the details for all organisation locations in their search results. The export is triggered by clicking on "export results" button at the end of the search result page (see *fig. 18*). Please note that the maximum number of results is 200. The details are exported as a csv file. See section 7.3 to learn about viewing the content of the csv file from an Excel file, in order to display the results correctly with special characters.

Export results with history - details exported include all historic versions of the same organisations and locations in the search result. The details are exported as a csv file.

The csv file includes the OMS data (including the extended Latin characters) in UTF-8 format; however, to view it correctly when using the MS Excel application the same steps as for exporting all organisations should be followed (see section 7.3)

- Perform search

- Export the file from OMS and proceed as per section 7.3

Figure 28. Export search results

As for export all organisations, the way to export the data differs between Google Chrome and Internet Explorer:

Figure 29. Export search results – Google Chrome - dowloads folder

Figure 30. Export search results – Internet Explorer – pop-up window to open or save

Again, the downloads file appears with the exported file

**Figure 31.** Open the downloads folder – csv. file
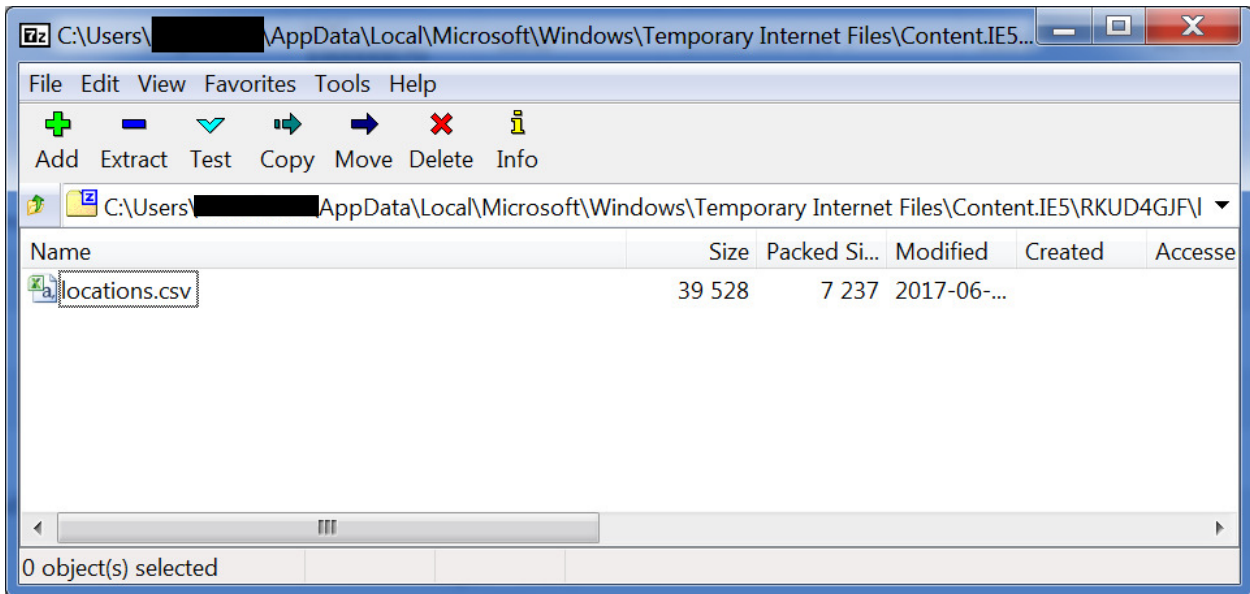
From here on, please proceed as per section 7.1.

7.5. Export organisation details

The web user can export organisation and location details. The details are exported as a csv file. The user has the option of exporting the organisation and location details shown on the screen only or also with all historic versions of the selected organisation and location.

A pop-up window shows for the user to open or save the file, then the following screen appears:

Figure 32. Export organisation and location details - csv file
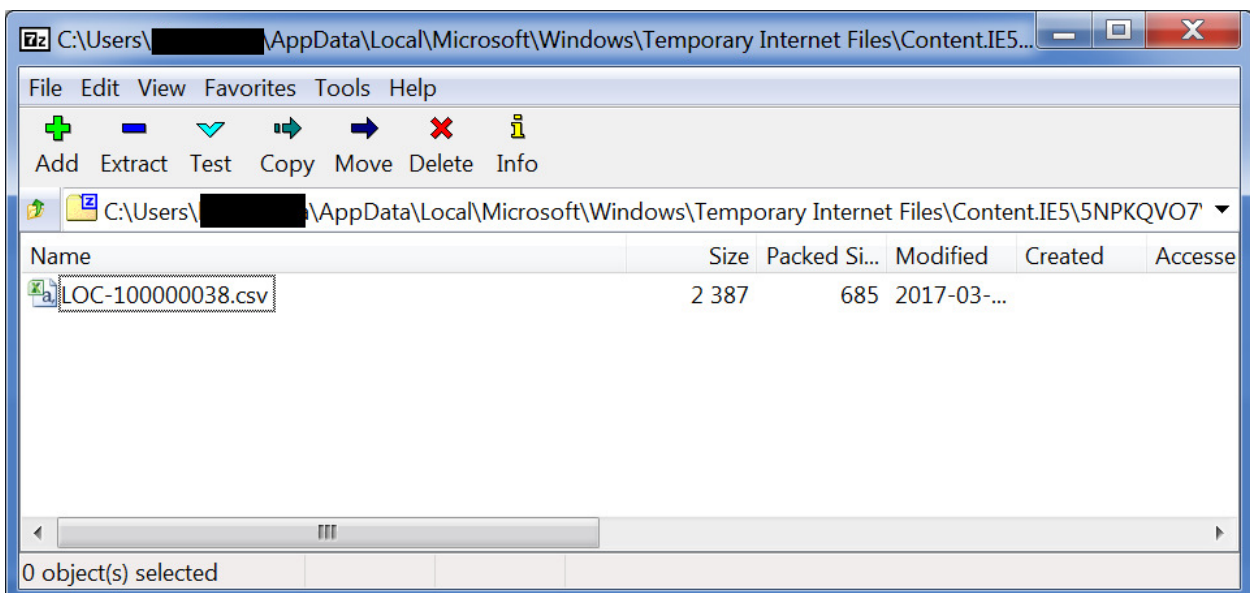
See section 7.3 to learn about how to view the content of the csv file from an Excel file.

8. Request new organisation, new location or request a change in organisation or location

8.1. Request options based on search result

Before submitting any request to the OMS, the user must search the available records. The option to request new organisation is only made available after a search is performed.

Based on the search results, the following options are available:

- If the user is <u>not able to find the requested organisation</u> – defined by name and country – they can **request creation of a new organisation**

- The request can be accessed directly from the search results page (once "No results found" message is displayed) or from View Organisation/Location Details page

Figure 33. No results found and option to request new organisation

Figure 34. Request new organisation from View Organisation Details

- If the <u>organisation is found, but the required location is not</u>, the requestor needs to submit a request to add a **new location to the existing organisation**

- This can be done from the search results screen or from the organisation/location details screen

Figure 35. Request new location for an existing organisation from the search results screen

Figure 36. Request new location for an existing organisation from the organisation/location details screen

- Alternatively, a user locates an <u>existing organisation and location</u>, but determines that the organisation and/or location <u>need to be changed</u>.

- In this situation the **"request a change"** process would be used to perform the change.

- The request for a change can include changes to

  o   Organisation name and acronym

  o   Location address (in EN)

  o   Location address (in non EN)

  o   Telephone and/or email

  o   DUNS and/or GS1 numbers

  o   Status of Organisation and/or Location i.e. this is for the inactivation of organisation and/or location.

- The change can be requested from the search results screen or from the organisation/location details screen

Figure 37. Request an organisation/location change from the search results screen

Figure 38. Request organisation/location change from the organisation/location details screen

After selecting an option to request a new organisation or request a change to an existing organisation, a change request form appears (see *fig. 41, 46 and 50*).

8.2. Change request process – general rules

8.2.1. Contact details

Contact details of the requestor (e.g. name, email address, telephone number) must be provided with all requests. The contact details allow OMS data stewards to contact the requestor in the event of there being queries relating to the new organisation/location. Only the requestor will be able to see these details after the request is submitted.

Contact details of the requestor will be pre-populated/defaulted as the form is opened. If required, the requestor can overwrite the default contact details, for example if they want a colleague to act as the contact for a particular request.

A user can request creation or update of any organisation or location; not only the one he or she is affiliated to.

8.2.2. Request generation

The requestor needs to fill in all mandatory fields on the request screen. For each of the request options mentioned above, the OMS Web Portal validates that all mandatory data (marked by a red asterisk) has been provided by the user, and issues appropriate error messages if any data is missing. If all mandatory data is present the request is submitted by the OMS Web Portal to the OMS.

Sufficient evidence needs to be provided to have the request approved. When creating a request, the user is able to upload documents (e.g. Word documents, PDFs) to support it. Requirements for the

submission of documentation are explained in 'Change request validation in OMS' in the 'view documents' page.

8.2.3. Request processing

Once the request has been submitted, the system sends an <u>email acknowledgement</u> to the requestor – using the contact details provided with the request – informing them that the request has been successfully received by OMS. The email acknowledgement contains the Request ID (ORQ-xxxxxxxxx) that has been assigned to the request.

The request receipt contains a link to the OMS page where the requestor can view the progress of the request. The user will need to be logged in to view their own requests.

Figure 39. Sample e-mail confirmation of request receipt with highlighted status and request ID
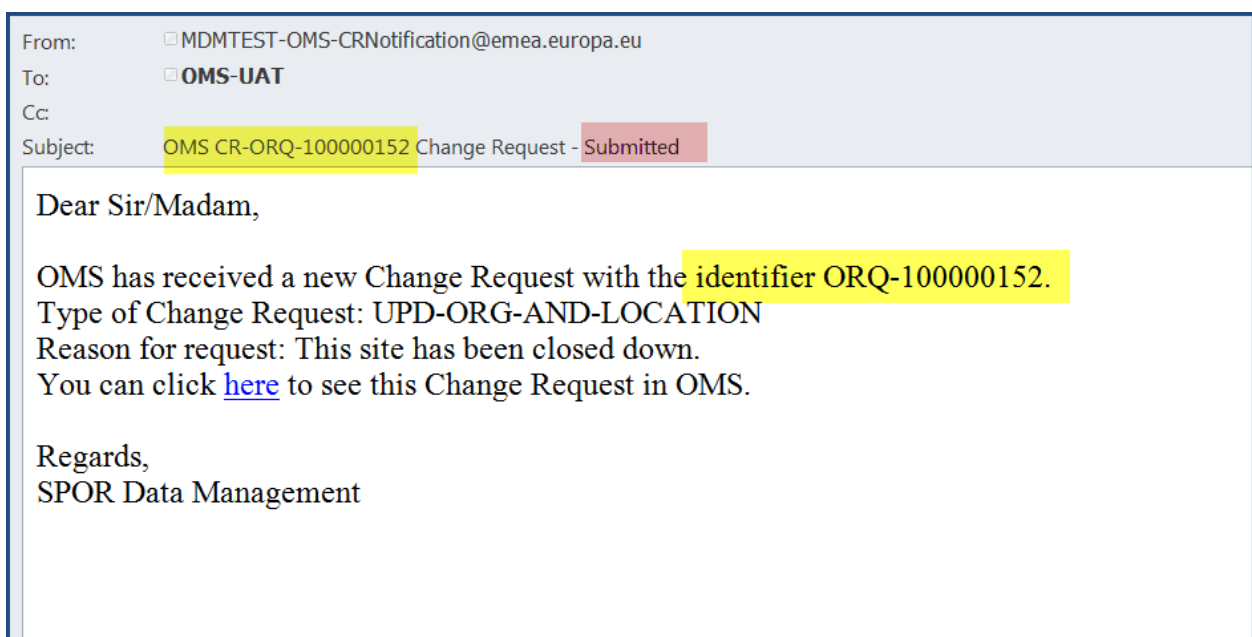
In case more information is needed to process the request, an e-mail is sent to the requestor, specifying the requirements and a deadline for reply.

When the request is <u>processed</u> by an EMA data steward, an <u>e-mail</u> is automatically sent to the request contact – using the contact information provided with the request - informing them that the request has been approved or rejected. The email includes the Request ID and the approval/rejection comment.

Figure 40. Sample e-mail confirmation of request approval with highlighted status and request ID
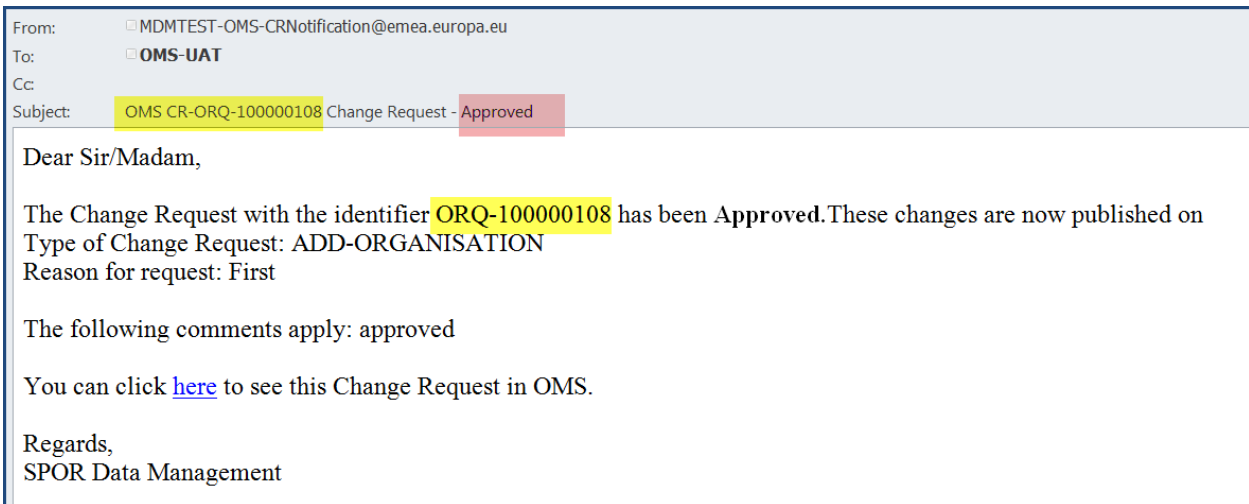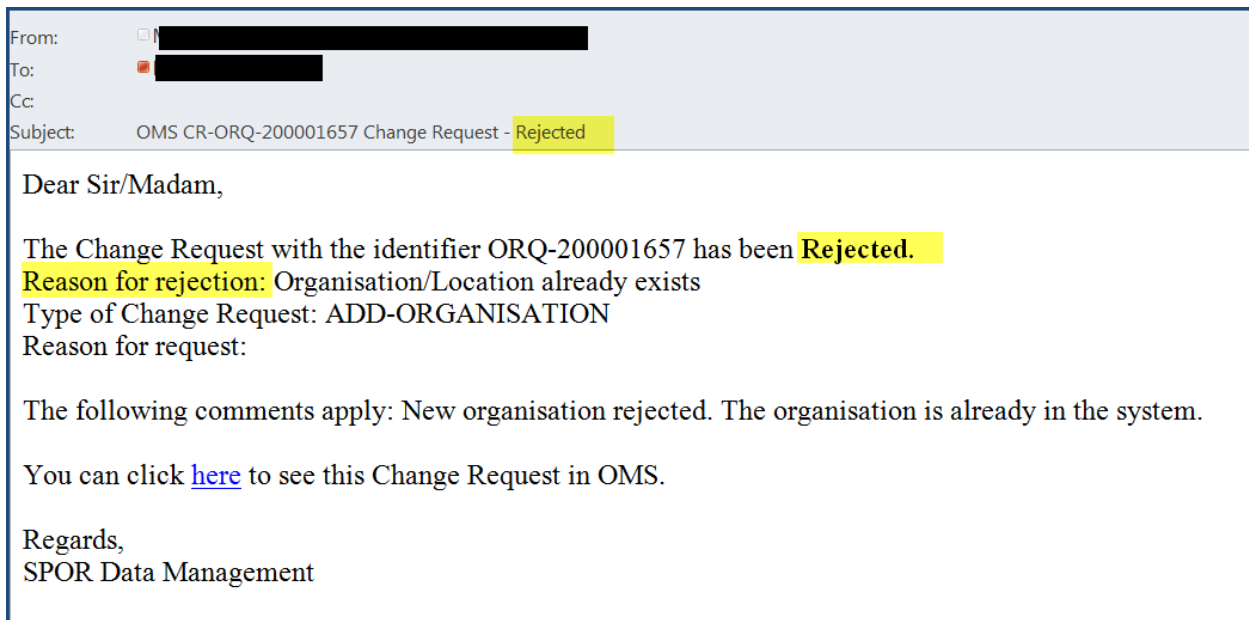

From: MDMTEST-OMS-CRNotification@emea.europa.eu
To: OMS-UAT
Cc:
Subject: OMS CR-ORQ-100000108 Change Request - Approved

Dear Sir/Madam,

The Change Request with the identifier ORQ-100000108 has been **Approved**. These changes are now published on
Type of Change Request: ADD-ORGANISATION
Reason for request: First

The following comments apply: approved

You can click here to see this Change Request in OMS.

Regards,
SPOR Data Management

Figure 41. Sample e-mail confirmation of request rejection with highlighted status

From:
To:
Cc:
Subject: OMS CR-ORQ-200001657 Change Request - Rejected

Dear Sir/Madam,

The Change Request with the identifier ORQ-200001657 has been **Rejected**.
Reason for rejection: Organisation/Location already exists
Type of Change Request: ADD-ORGANISATION
Reason for request:

The following comments apply: New organisation rejected. The organisation is already in the system.

You can click here to see this Change Request in OMS.

Regards,
SPOR Data Management

The confirmation contains a link where the requestor can view the request process.

8.3. Request new organisation

When raising a request to create a new organisation the requestor is required to provide data for the organisation (e.g. organisation name and organisation type), and the physical location (e.g. address). In addition, other Location related information can be provided such as telephone number, email address, DUNS and/or GS1 numbers.

Only data for a single location can be provided with each request; therefore, if a new organisation requires multiple locations a request must initially be raised to create the organisation and its initial location. Once the new organisation has been approved, additional requests need to be raised to add the additional locations (one request per location).

Figure 42. Request new organisation – screen overview with highlighted areas for change request information, organisation details, location details and attachments

Figure 43. Request new organisation – form

Business rules:

- Mandatory fields are marked by red asterisk

- The CR type is "New Organisation" and cannot be changed

- Request reason needs to be chosen from the drop-down list as appropriate. Please note that it covers the comments and requestor details when expanded; it collapses after a choice is made

Figure 44. Request reason – new organisation

- Organisation is country specific – i.e. the country of the first location determines the country for all associated locations

- Preferred language is English. Organisation and location details can also be entered in other EEA official[1] languages but the system will supplement the record with English transcription where possible

- The Agency is not responsible for the correctness of information in Greek and Bulgarian which is submitted in Greek and Cyrillic characters. OMS dictionary will store and validate information on Greek and Bulgarian addresses as long as it is in Latin characters (transliterated). Once the addresses in Latin characters are validated, the OMS mastering tool will automatically generate Greek and Cyrillic versions of the address. There is no need to request the creation of these addresses using Greek and Cyrillic characters unless corrections are necessary.

- E-mail addresses must contain "@" and "."

- Organisation type is a drop-down list – the requestor needs to choose what is most appropriate from the options available. Please note that it covers the address when expanded; it collapses after a choice is made

Figure 45. Organisation type drop-down list

- Contact phone numbers needs to contain the country code

- DUNS number and GS1 number are not mandatory but should be provided if available as they provide data quality reassurance

- Once submitted, the request cannot be edited or resubmitted

Attachments:

- To support a change request, documents must be submitted to allow the EMA data stewards to validate the request

- The documents are added in the 'Attachments' section of the request form on the right hand side of the new organisation screen (see *fig. 45*) by clicking on "+" symbol

Figure 46. Attachments

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[1] European Economic Area

8.4. Request new location to an existing organisation

New location can be added to an existing organisation by this process. The requestor is required to provide data for the new physical location (i.e. address, phone/e-mail, DUNS/GS1 numbers).

Only data for a single location can be provided with each request; therefore, if a new organisation requires multiple locations a request must initially be raised to create the organisation and its initial location. Once the new organisation has been approved additional requests need to be raised to add the additional locations (one request per location).

Figure 47. Add new location to an existing organisation – screen overview with highlighted areas for change request information, organisation details, location details and attachments

Figure 48. Request new location for an existing organisation – form

If the addition of the location is as a consequence of that (physical) location being taken over by the selected organisation, select the request reason "create a new organisation – split from existing organisation'. In the comments/supporting documentation, identify from which organisation (with OMS Organisation ID) the mentioned location needs to be moved under the selected organisation in the change request.

Business rules:

- Mandatory fields are marked by red asterisk

- The CR type is "add location" and cannot be changed

- Request reason needs to be chosen from the drop-down list as appropriate. Please note that it covers the comments and requestor details when expanded; it collapses after a choice is made

Figure 49. Request reason – add new location

- Organisation type is entered on the organisation level and is the same for all locations – therefore, the field is not editable

- Organisation is country specific – i.e. the country of the organisation determines the country for all associated locations. Therefore, the country is not editable

- If the requested location is not in the same country as the first location, please request creation of a new organisation

- Preferred language is English. Organisation and location details can also be submitted in other EEA official languages but the system will supplement the record with English translation/transcription where possible

- The Agency is not responsible for the correctness of information in Greek and Bulgarian which is submitted in Greek and Cyrillic characters. OMS dictionary will store and validate information on Greek and Bulgarian addresses as long as it is in Latin characters (transliterated). Once the addresses in Latin characters are validated, the OMS mastering tool will automatically generate Greek and Cyrillic versions of the address. There is no need to request the creation of these addresses using Greek and Cyrillic characters unless corrections are necessary.

- E-mail addresses must contain "@" and "."

- Contact phone numbers need to contain the country code

- DUNS number and GS1 number are not mandatory but should be provided if available as they provide data quality reassurance

- Once submitted, the request cannot be edited

Attachments:

- To support a new organisation request, documents can be submitted to confirm the organisation existence and the details

- The documents are added in the 'Attachments' section of the request form on the right hand side of the new organisation screen (see *fig. 49*) by clicking on "+" symbol

Figure 50. Attachments

8.5. Update organisation or location

The user can request an update to organisation or location details.

If there is a pending change for the organisation but not the location in the system, then the details of the organisation are read only and an explanatory message is displayed; e.g. "you can only request a change to the location details as there is already a change pending for the organisation".

If there is a pending change for the location in the system, then all the location details are read only and an explanatory message is displayed; e.g. "you cannot request a change currently as there is already a change pending".

Figure 51. Update organisation or location - screen overview with highlighted areas for change request information, organisation details, location details and attachments

Figure 52. Update organisation and/or location – form

Business rules:

- Mandatory fields are marked by red asterisk

- The default CR type is "update organisation and location". If the user edits only the organisation data, the system will automatically change the CR type to 'update organisation'. If the user changes only location data, then the CR type will change to 'update location'. If the user updates both, then the CR type will remain as the default value.

- Request reason needs to be chosen from the drop-down list as appropriate. Please note that it covers the comments and requestor details when expanded; it collapses after a choice is made

Figure 53. Request reason – update organisation and location

- Preferred language is English. Organisation and location details can also be entered in other EEA official languages but the system will supplement the record with English transcription where possible

- Organisation type is recorded upon the first organisation data entry and is the same for all locations – therefore, the field is not editable

- Organisation is country specific – i.e. the country of the organisation determines the country for all associated locations. Therefore, the country is not editable

- E-mail addresses must contain "@" and "."

- Contact phone numbers need to contain the country code

- DUNS number and GS1 number are not mandatory but should be provided if available as they provide data quality reassurance

- Once submitted, the request cannot be changed

Attachments:

- To support a new organisation request, documents can be submitted to confirm the organisation existence and the details

- The documents are added in the 'Attachments' section of the request form on the right hand side of the new organisation screen (see *Fig. 53*) by clicking on "+" symbol

Figure 54. Attachments

9. View requests

- Once submitted, the requests cannot be edited, only viewed.

- Requests can be viewed either from the OMS landing page or from any other screen as the top bar always remains the same

- Only the user who sends the request can view that request

☞ *Please note that the requested data is displayed in this view, not the data which is published in the OMS as a result of the request.*

Figure 55. View requests – from the OMS landing page

The user can see a list of their active and historic requests and optionally also the details of each request, after clicking on the magnifying glass or on the address link

- The request status is displayed – submitted, approved, approved with change, rejected, on hold (i.e. information requested from the user)

- CR type – ADD-ORGANISATION, ADD-LOCATION, UPD-ORGANISATION, UPD-LOCATION, UPD-ORGANISATION-LOCATION

- The columns can be sorted

- Default sort order is the change request date

- The user can choose 20, 50 or 100 results

- The maximum number the user can see is the first 500 requests

Figure 56. View requests (no edit mode) and sorting by CR date

There can be more than 1 page of results.

Figure 57. Number of results and pagination of results

Examples of requests expanded for viewing:

Figure 58. Overview of the request page – includes request status

Figure 59. View request details – new organisation

Figure 60. View request details – update location

Figure 61. View request details – request rejected

In addition, the user will be able to export the request data in csv format. This is for individual requests as well as the request list.

Figure 62. Exporting requests

A pop-up window shows for the user to open or save the file, then the following screen appears:

Figure 63. Exporting change requests
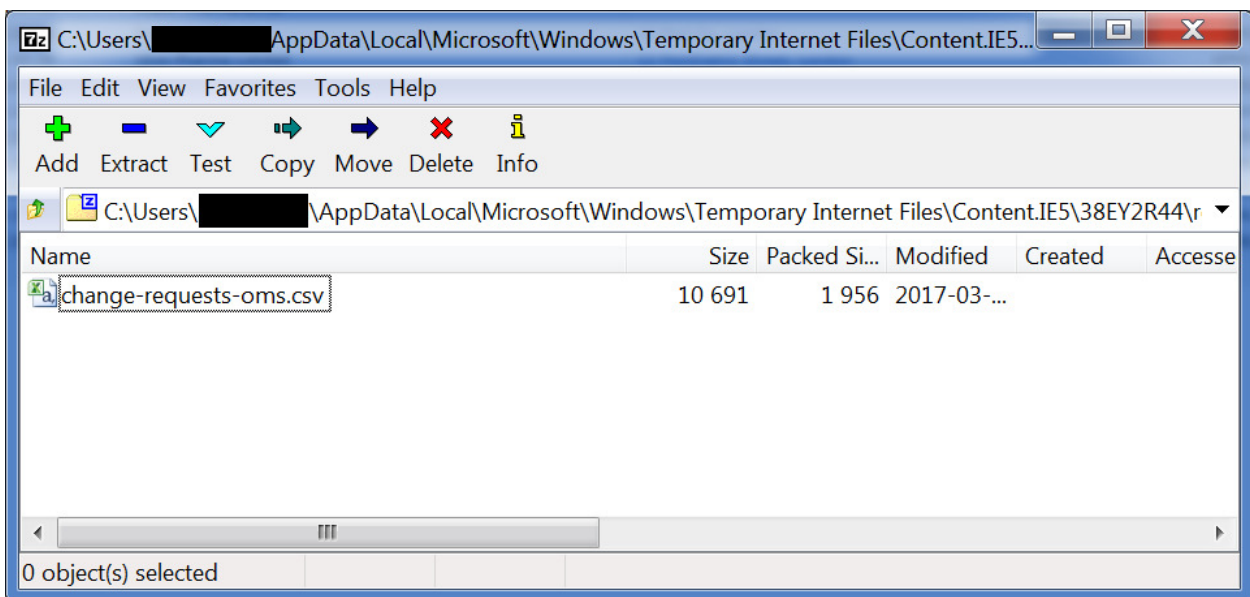
See section 7.3 to learn how to view the content of the csv file from an Excel file.

10. Technical support for OMS

Technical support for the OMS is provided by the EMA Service Desk that also authorises OMS super user access.

IT Service Desk link:

https://servicedesk.ema.europa.eu

In order to request support, the user should log in with their EMA log in and password.

The technical support can be requested in the following categories

- For general or business-related questions on SPOR, click on "Ask a Question" link in the screen below

- For any technical/software-related issues, click on "Report an Issue" (as shown in the screen below) and on "Report an issue with business applications/software" in the next screen

- To request SPOR Super User access, click on "Request a Service" and follow the instructions provided in the document "SPOR user registration manual."

Figure 64. IT Service Desk interface
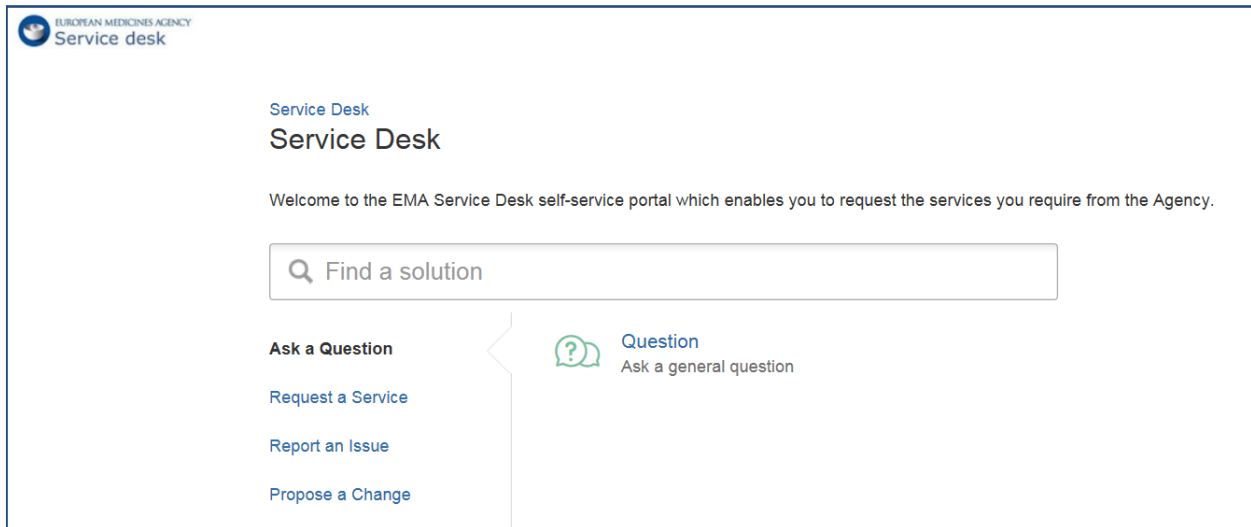
11. Reference documents - tbc

SPOR

OMS

IAM (IIQ)

Tbc