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# **EUTCT - Change Request Process**

## Introduction

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This page describes the process for Change Requests to EUTCT. It does not describe the detail of how to use the various screen of the application, these are available here in the Help system.

### Type of lists

The Controlled Term Lists in EUTCT fall into the following categories:

- Internally Managed Controlled Term Lists with Change Requests
- Internally Managed Controlled Term Lists without Change Requests
- Externally Managed Controlled Term Lists – EUTCT routing Change Requests
- Externally Managed Controlled Term Lists – direct Change Requests

### Actors

#### Change Requestor

The Change Requestor is someone that requests a new Controlled Term, the deletion of a Controlled Term or a change to a Controlled Term that the EUTCT system manages.

#### EUTCT Secretariat

The EUTCT Secretariat is responsible for managing all changes to the Controlled Terms that the EUTCT system contains.

#### External List Owner

An External List Owner is an organisation external to the EMEA that manages Controlled Term Lists (CTLs). Examples are: EDQM, ISO, MSSO and CVMP.

#### Terminology Evaluation Group

Each Terminology Evaluation Group comprises a number of experts (known as Terminology Evaluation Group Members) in a given field from the NCAs. Their role is to evaluate any Change Request for a new, changed or removed Controlled Term.

Note that for this release the role of the Terminology Evaluation Group will be performed by the Terminology Sub-Group of the EUTCT Project

## Internally Managed Controlled Term Lists with Change Requests

### Type of Change Requests

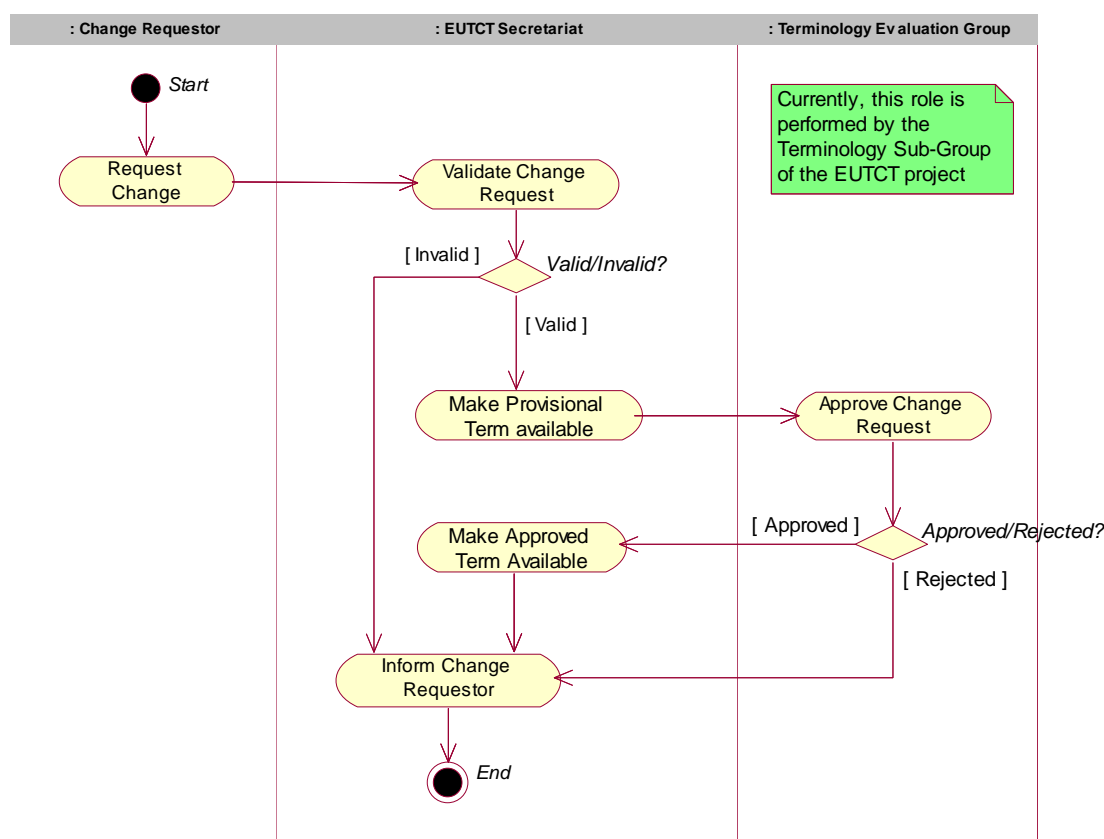
You can make the following types of Change Requests on this Controlled Term List:

- New, to create a Controlled Term
- Update, to modify one or more attributes of a Controlled Term
- Remove, to make a Controlled Term “Non-Current”.

Note that you can only make Update and Remove Change Requests on Controlled Terms that have a status of “Current”.

### EUTCT standard Change Request Process

The following diagram shows the EUTCT standard Change Request Process for Internally Managed Controlled Term Lists.



### Request Change Process

You should use the following steps to request a change to a Controlled Term List:

1. Ensure you have the Change Requestor role. If not contact the person in your organisation with this role.
2. Check List Info to see if you can apply for a CR on the CTL
3. Verify that the type of CR is valid for the CTL
4. Look up the justification and supporting documentation required and obtain electronic copies of the documentation.
5. Complete the Change Request electronically in the EUTCT System.
6. Submit the CR
7. The system will send you an email to acknowledge receipt of the Change Request and give you its reference number. You can use this number to track your Change Request in the system.

## **Validate Change Request Process**

The EUTCT Secretariat will use the following steps to validate your Change Request:

1. The EUTCT Secretariat verifies that you have entered a justification and provided supporting documentation in accordance with the List Information.
2. If the information is correct they mark the Change Request as Valid and it moves to the approval step of the process.
3. If your Change Request is for a new Controlled Term, the system enters this into the relevant Controlled Term List with the status of Provisional at the same time as the previous step.
4. The system sends an email notifying you that the Change Request is Valid and giving you the Term Identifier of the provisional Controlled Term.
5. If the Change Request is Invalid, the Secretariat enters information explaining why this is and marks the Change Request as Invalid. The system then sends you an email saying that the Change Request is Invalid and includes the reasons provided.
6. You can then use the information provided by the Secretariat to prepare and submit a new Change Request.

## **Approval Process**

The EUTCT Terminology Evaluation Group<sup>1</sup> will use the following steps to approve your Change Request:

1. The EUTCT Terminology Evaluation Group verifies that you have entered a valid scientific argument and provided the adequate supporting documentation in accordance with the List Information. For Update and Remove Change Requests they also consider the impact it might cause to the existing Controlled Terms.
2. If the information is acceptable they mark the Change Request as Approved.
3. The system sends an email notifying you that your Change Request is Approved.
4. If the Change Request is rejected, the EUTCT Terminology Evaluation Group enter information explaining why this is and marks the Change Request as Rejected.
5. The system then sends you an email saying that the Change Request is rejected and includes the reasons provided.
6. You can then use the information provided by the EUTCT Terminology Evaluation Group to prepare and submit a new Change Request.
7. The EUTCT Terminology Evaluation Group may also approve the Change Request provided that certain changes are made to the term. In this case the Terminology Evaluation Group integrates the changes and explains why they have been made.

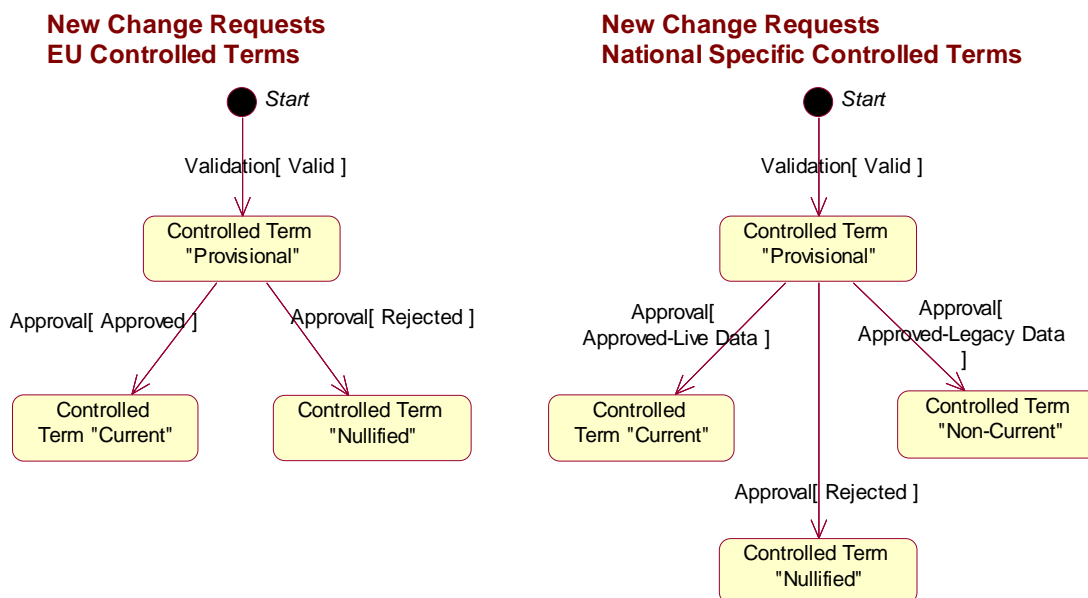
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<sup>1</sup> Note that for this release the role of the Terminology Evaluation Group will be performed by the Terminology Sub-Group of the EUTCT Project.

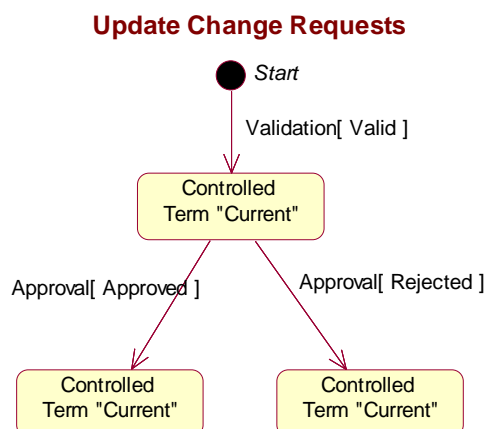
## Controlled Term Status Changes during Change Request Process

The following diagrams show the way the Controlled Term status changes during the Change Request process.

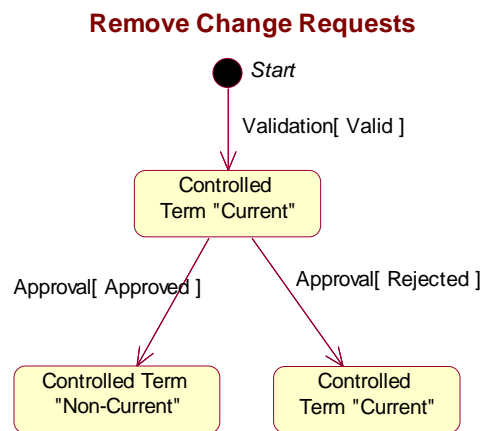
### New Change Requests



### Update Change Requests



## Remove Change Requests



## **Internally Managed Controlled Term Lists without Change Requests**

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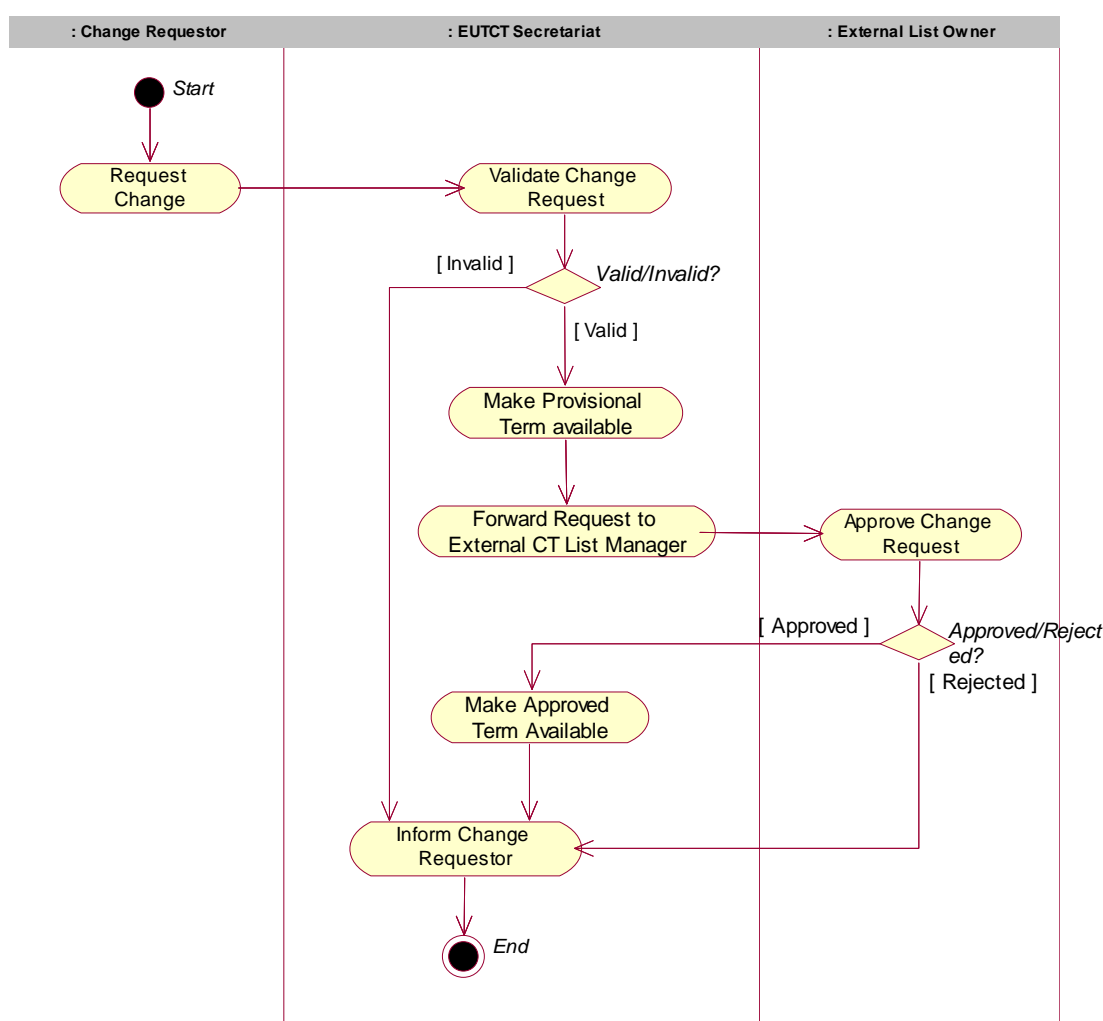
EUTCT contains a number of Controlled Term Lists where Change Requests will not be accepted because these are under the control of the EUTCT Secretariat.

## Externally Managed Controlled Term Lists – EUTCT routing Change Requests

The Controlled Terms in this Controlled Term List are managed by and under the change control process of the External List Owner

EUTCT will accept change requests concerning the controlled terms, issue EUTCT Provisional Controlled Terms and will route the requests through to the External List Owner for approval.

In addition, EUTCT will accept Change Requests for National Specific Controlled Terms. EUTCT does not recommend updates on National Specific Controlled Terms and recommends they be made “Non-Current”.



### Request Change Process

You should use the following steps to request a change to a Controlled Term List:

1. Ensure you have the Change Requestor role. If not contact the person in your organisation with this role.



2. Verify that the type of CR is valid for the CTL
3. Look up the justification and supporting documentation required and obtain electronic copies of the documentation.
4. Complete the Change Request electronically in the EUTCT System.
5. Submit the CR
6. The system will send you an email to acknowledge receipt of the Change Request and give you its reference number. You can use this number to track your Change Request in the system.

## **Validate Change Request Process**

The EUTCT Secretariat will use the following steps to validate your Change Request:

1. The EUTCT Secretariat verifies that you have entered a justification and provided supporting documentation in accordance with the List Information.
2. If the information is correct they mark the Change Request as Valid and it moves to the approval step of the process.
3. If your Change Request is for a new Controlled Term, the system enters this into the relevant Controlled Term List with the status of Provisional at the same time as the previous step.
4. The system sends an email notifying you that the Change Request is Valid and giving you the Term Identifier of the provisional Controlled Term.
5. If the Change Request is Invalid, the Secretariat enters information explaining why this is and marks the Change Request as Invalid. The system then sends you an email saying that the Change Request is Invalid and includes the reasons provided.
6. You can then use the information provided by the Secretariat to prepare and submit a new Change Request.

## **Approval Process**

The External List Owner will use their standard process to approve your Change Request.

If the Change Request is rejected then you can raise another Change Request for the Controlled Term as a National Specific Controlled Term. In this case the process for the Internally Managed Controlled Term List applies. Ensure that you provide all the necessary information, including the information for a National Specific Controlled Term and the original Change Request ID.

## **Externally Managed Controlled Term Lists – direct Change Requests**

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EUTCT will not accept any Change Requests on these Controlled Term Lists since they are under the change control process of the External List Owner. You can find more information by following the links in the List Information.

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## Information required on the Controlled Term

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All mandatory fields for the Controlled Term should be completed. In addition, you should provide information in the following fields:

- A description of the Controlled Term if the other Controlled Terms in the list contain descriptions.
- A short name for the Controlled Term if applicable.
- A translation of the proposed names in your Member State language.
- Proposed replacement terms if the Controlled Term is to be made “Non-Current” (if applicable).