

## **Linguistic check of the translations of the summary of product characteristics (SPC) of Union authorisation applications of a same biocidal product**

Version 2.0

The purpose of this document is to describe the procedure for the linguistic check of SPC translations for Union authorisation (UA) applications of a same biocidal product (SBP), outlining the responsible actors and deadlines. The procedure covers both types of UA application of an SBP: UA applications of an SBP in parallel to a UA (UA-BBP) and UA applications of an SBP in sequence of a UA (UA-BBS).

## Document history

Document history			
Version	Changes	Date	Date of applicability <sup>1</sup>
1.0	First edition	24 November 2022 at BPC-45	3 January 2023
2.0	Major changes in the document: <ul style="list-style-type: none"><li>• Revision of the linguistic check procedure for UA-BBP and UA-BBS. The procedures were separated and further details included.</li><li>• Update of flowcharts.</li><li>• Adjustment of timelines.</li><li>• Transition from SPC Editor to SPC in IUCLID</li><li>• Editorial changes</li></ul>	26 February 2024 at BPC-50	22 March 2024

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<sup>1</sup> This is the date when the document is published on the ECHA website

## 1. Introduction

The same biocidal product Regulation<sup>2</sup> requires the submission of a summary of the product characteristics (SPC) for the same biocidal product as part of the authorisation application (Article 2(d) of the SBP Regulation). For a UA of an SBP, the SPC has to be translated in all the official languages of the Union before the authorisation is granted and the translations are to be made available to the European Commission (COM) in accordance with Article 44(4) of the BPR<sup>3</sup>. This article finishes with the wording “where applicable” which is interpreted as meaning that the translation of the draft SPC is only required when the ECHA opinion supports granting an authorisation.

In this context, the responsible actor for making the SPC translations available to the European Chemicals Agency (ECHA) is the applicant.

The SPC of a UA of an SBP must be identical to the SPC of the related reference UA with the exception of information that can be the subject of an administrative change in accordance with the Changes Regulation<sup>4</sup> (CR) (Articles 1 and 7 of the SBP regulation). Accordingly, the same applies to SPC translations of a UA of an SBP, which should be identical to the SPC translations of the related reference UA with the exception of information that can be the subject of an administrative change in accordance with the CR.

## 2. Initial considerations and process implementation

Considering the short timeframe for the submission of SPC translations, the applicant of the UA of an SBP must monitor its R4BP 3 account on a regular basis to be aware as soon as possible of any incoming communications or tasks and liaise closely with the applicant of the related reference UA to obtain from them the latest versions of the SPC files throughout the application process.

The basis for the SPC and its translations for the UA application of an SBP is the SPC of the related reference product or product family. The languages required for the SPC translations are all the official languages of the Union<sup>5</sup>, as well as Norwegian and Icelandic<sup>6</sup>.

When requested by ECHA, the SBP applicant must commit to providing SPC translations that are identical to the SPC translations of the reference UA with the exception of sections that are affected by administrative changes. These changes must be correctly listed in the supporting document provided during the submission of the application. Before submitting the SPC translations to ECHA, the SBP applicant must ensure that they comply with these requirements by comparing their SPC files with the ones of the reference application using the comparison tool available in IUCLID. In case the SPC or its translations are not correctly aligned with the SPC and the translations of the related reference UA, or include changes not reported in the supporting document, the SBP applicant will have seven

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<sup>2</sup> Commission implementing Regulation (EU) No 414/2013

<sup>3</sup> Regulation (EU) No 528/2012

<sup>4</sup> Commission implementing Regulation (EU) No 354/2013

<sup>5</sup> Irish is an official language of the EU. Since the derogation from the Council Regulation (EC) 920/2005 is phased out, the SPCs should be translated in Irish as from 1 January 2021.

<sup>6</sup> Article 20(3) of the BPR and Chapter XV of Annex II to the EEA agreement.

calendar days to provide an acceptable English (EN) SPC and SPC translations. This will result in a delay of the transmission to the Commission (COM) of the SPC translations and it will delay the date when the UA application of an SBP authorisation will be granted.

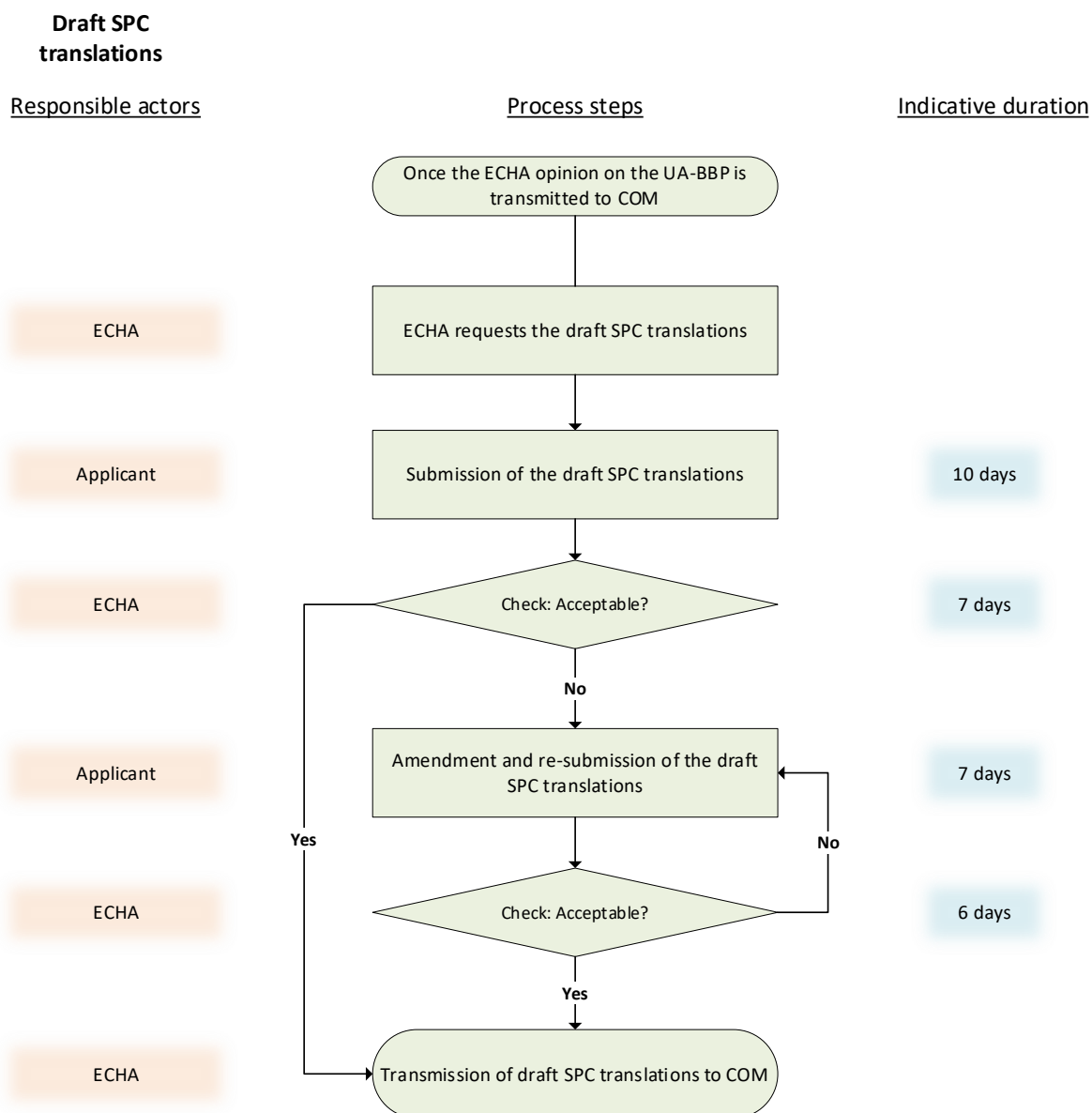
In case the UA application of an SBP includes fewer meta SPC than the reference UA, SBP applicants must ensure that any irrelevant references to meta SPC not included in their application are removed from the SPC.

For a faster processing, the applicants of UA-BBS applications may provide the SPC translations already when submitting their UA-BBS application to ECHA.

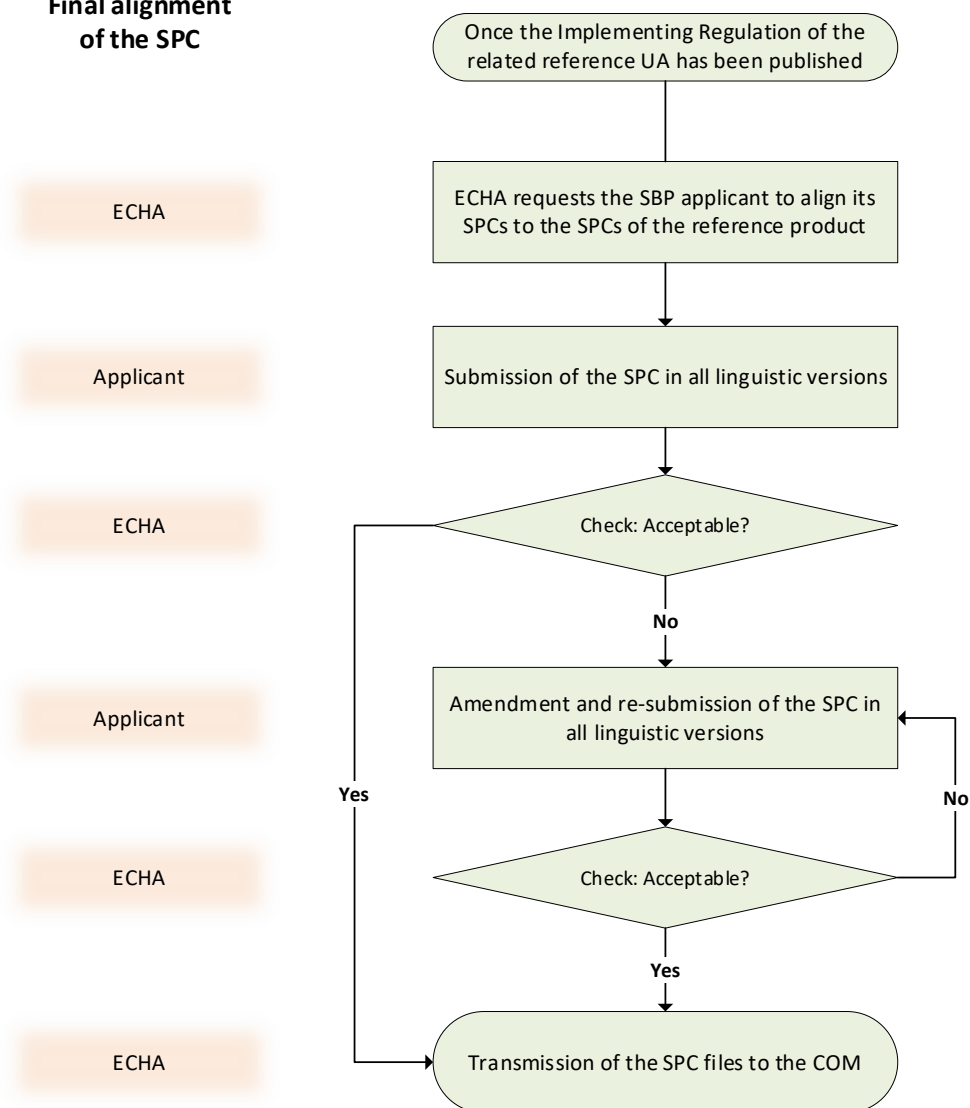
### 3. Steps for the linguistic check of the SPC translations of UA applications of an SBP

For UA-BBP, the applicant is required to provide the draft SPC translations once the ECHA opinion on the UA-BBP has been transmitted to COM. At a later date, the UA-BBP applicant is required to do a final alignment of all the linguistic versions of the SPC once all the SPCs of the related reference UA have been updated following the publication of the Implementing Regulation of the related reference UA. The different steps are outlined in Figure 1 and Table 1 of this document.

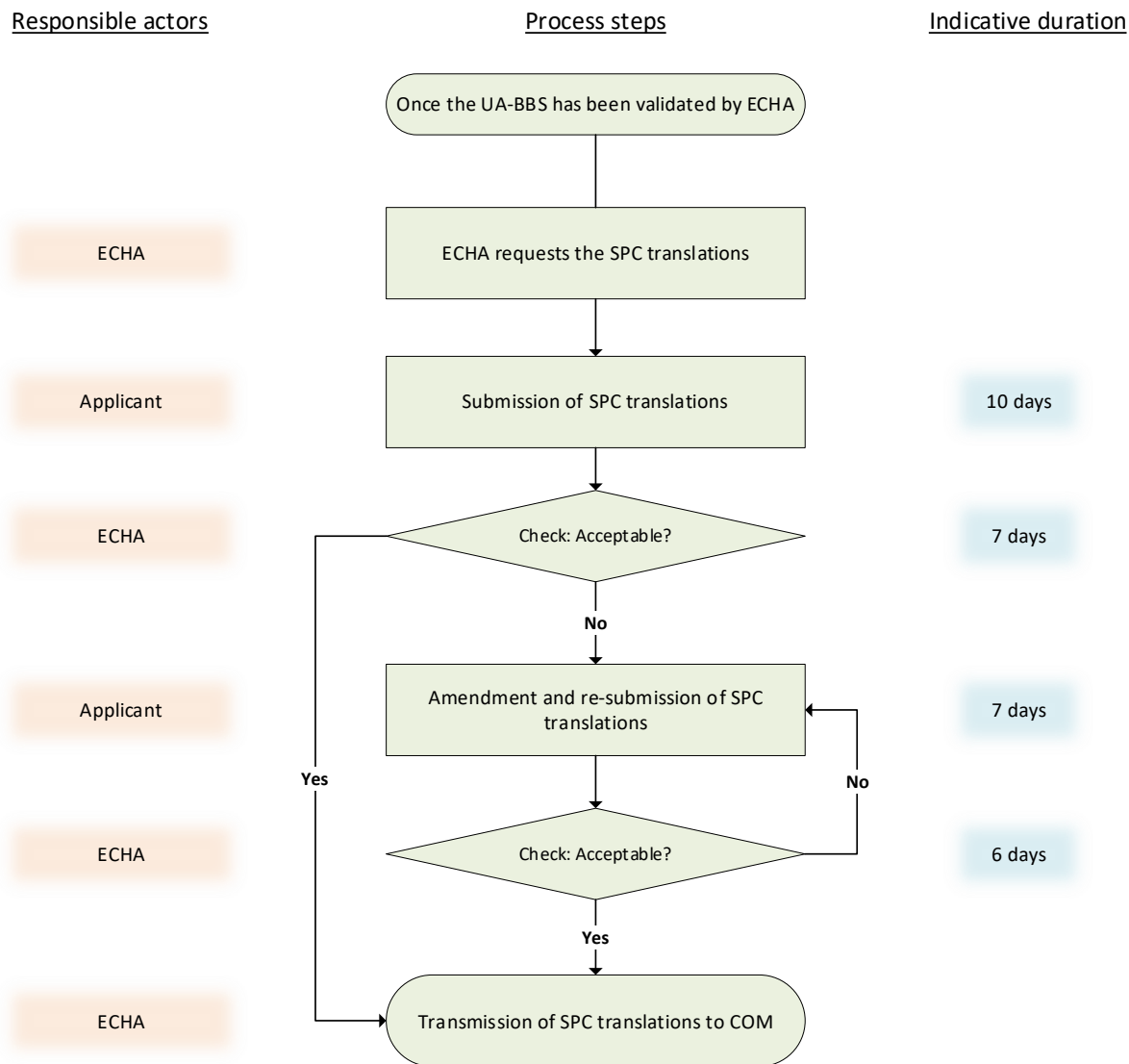
**Figure 1. Flowchart of the linguistic check process for UA applications of an SBP in parallel of a UA (UA-BBP)**



**Final alignment  
of the SPC**



**Figure 2. Flowchart of the linguistic check process for UA applications of an SBP in sequence of a UA (UA-BBS)**



The steps and the relevant indicative deadlines for the check of the SPC translations of UA-SBP are listed in tables 1 and 2 below. The durations are given in calendar days.

**Table 1. Steps for UA applications of an SBP in parallel of a UA (UA-BBP)**

<b>Step</b>	<b>Linguistic check of SPC translations (UA-BBP)</b>	<b>Responsible actor</b> (Indicative time limit)
<b>1.</b>	<b>Submission of the draft SPC translations</b>	
	Once the ECHA opinion on the UA-BBP has been transmitted to COM, ECHA requests the SBP applicant to submit the draft SPC translations for their application. The request will be sent via R4BP 3.	<b>ECHA</b>  (Without undue delay)
	The applicant submits the draft SPC translations in .i6z format to ECHA via R4BP 3 within the deadline given by ECHA.  The SPC in all linguistic versions must be identical to those of the related reference UA application, with the exception of information that can be subject to an administrative change. These changes must be listed in the supporting document provided during the submission of the application.  Before submitting the draft SPC translations to ECHA, the applicant must ensure that they comply with these requirements by comparing their SPC translations with the ones of the reference application using the available comparison tool in IUCLID.	<b>Applicant</b>  (Within 10 days)
<b>2.</b>	<b>Linguistic check</b>	
	ECHA assesses whether the translations of the sections of the SPCs not affected by administrative changes are identical to the SPC translations of the related reference UA.  If any of the translations is not identical in these sections, ECHA will return <b>all</b> linguistic versions of the SPC to the applicant and request an identical translation via R4BP 3 at the latest 6 days after ECHA has received the SPC translations.	<b>ECHA</b>  (7 days)
<b>3.</b>	<b>Resubmission of the draft SPC translations (when applicable)</b>	
	The applicant will amend the draft SPC translations and reply by submitting all linguistic versions of the SPC in .i6z format within the given deadline to ECHA via R4BP 3.  ECHA will reinitiate the check of the SPC translations (step 2) and will conclude the check within 6 days.	<b>Applicant</b>  (Within 7 days)
<b>4.</b>	<b>Transmission of the draft SPC translations to COM</b>	



Step	Linguistic check of SPC translations (UA-BBP)	Responsible actor (Indicative time limit)
	ECHA transmits to COM the draft SPC translations in .i6z format via R4BP 3 with the exception of the Norwegian and Icelandic translations. These translations will be used directly by the relevant MSCA (Norway or Iceland) instead.	<b>ECHA</b>  (Without undue delay)
<b>5.</b>	<b>Final alignment of the SPCs in all linguistic versions</b>	
	<p>Once all the SPCs of the related reference UA have been updated following the publication of the Implementing Regulation of the related reference UA, ECHA requests the SBP applicant to update and submit the English SPC and SPC translations for their application such that they are aligned with the final versions of the SPC files of the related reference UA.</p> <p>In order to facilitate the final alignment of the SPCs for the SBP applicants, ECHA may provide the final SPC files of the related reference UA for the SBP applicant to include their administrative differences.</p> <p>The applicant submits all the linguistic versions of the SPC in .i6z format to ECHA via R4BP 3 within the deadline given by ECHA.</p> <p>The SPC in all linguistic versions must be identical to those of the related reference UA application, with the exception of information that can be subject to an administrative change. These changes must be listed in the supporting document provided during the submission of the application.</p> <p>Before submitting the SPC files to ECHA, the applicant must ensure that they comply with these requirements by comparing their SPC files with the ones of the reference application using the available comparison tool in IUCLID.</p> <p>If any of the translations is not identical in these sections, ECHA will return <b>all</b> linguistic versions of the SPC to the applicant and request an identical translation via R4BP 3.</p>	<b>ECHA Applicant</b>

**Table 2. Steps for UA applications of an SBP in sequence (UA-BBS)**

Step	Linguistic check of SPC translations (UA-BBS)	Responsible actor (Indicative time limit)
<b>1.</b>	<b>Submission of SPC translations</b>	
	After ECHA has validated the application, ECHA requests the SPC translations from the SBP applicant via R4BP 3 unless the SPC translations were already provided at the submission of the UA-BBS application.	<b>ECHA</b>  (Without undue delay)

<b>Step</b>	<b>Linguistic check of SPC translations (UA-BBS)</b>	<b>Responsible actor</b> (Indicative time limit)
	<p>The applicant provides the SPC translations in .i6z format to ECHA via R4BP 3 within the deadline given by ECHA.</p> <p>The SPC translations must be identical to those of the related reference UA application, with the exception of information that can be subject to an administrative change. These changes must be listed in the supporting document provided during the submission of the application.</p> <p>Before submitting the SPC translations to ECHA, the applicant must ensure that they comply with these requirements by comparing their SPC translations with the ones of the reference application using any available comparison tool.</p>	<p><b>Applicant</b> (Within 10 days)</p>
<b>2.</b>	<p><b>Linguistic check</b></p> <p>ECHA assesses whether the translations of the sections of the SPC not affected by administrative changes are identical to the SPC translations of the related reference UA.</p> <p>If any of the translations is not identical in these sections, ECHA will return <b>all</b> SPC translations to the applicant and request an identical translation via R4BP 3.</p>	<p><b>ECHA</b> (7 days)</p>
<b>3.</b>	<p><b>Resubmission of SPC translations (when applicable)</b></p> <p>The applicant will amend the draft SPC translations and reply by submitting all linguistic versions of the SPC in .i6z format within the given deadline to ECHA via R4BP 3.</p> <p>ECHA will reinitiate the check of the SPC translations (step 2) and will conclude the check within 6 days.</p>	<p><b>Applicant</b> (Within 7 days)</p>
<b>4.</b>	<p><b>Transmission of final SPC translations</b></p> <p>ECHA transmits the final SPC translations to COM in .i6z format via R4BP 3 with the exception of the Norwegian and Icelandic translations. These translations will be used directly by the relevant MSCA (Norway or Iceland) instead.</p>	<p><b>ECHA</b> (Within legal deadline)</p>