

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

Version 1.0

Document history

Document history		
Version	Changes	Date
1.0	First edition	24 November 2022

1. Introduction

The same biocidal product Regulation¹ requires the submission of a summary of the product characteristics (SPC) for the same biocidal product as part of the authorisation application of SBP (Article 2(d) of the SBP Regulation). For Union authorisation (UA) of SBP, the SPC has to be translated in all the official languages of the Union before the authorisation is granted. In this context, the responsible actor for making the SPC translations available to ECHA is the applicant.

The SPC of a UA of 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 Change Regulation² (CR) (Articles 1 and 7 of the SBP regulation). Accordingly, the same applies to SPC translations of a UA of 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.

The aim of this document is to describe the procedure for the linguistic check of the SPC translations for UA applications of SBP, outlining the responsible actors and deadlines.

2. Initial considerations and process implementation

Considering the short timeframe for the submission of the translations, the applicant of the UA of SBP must contact well in advance the applicant of the related reference UA to obtain from them the final SPC in all linguistic versions as soon as they are finalised. These constitute the starting point for the SPC and its translations for the UA application of SBP as all linguistic versions of the SPC, including the English version, need to be aligned with the final voted SPC of the related reference application.

When requested by ECHA, the applicant must commit to provide 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 listed in the supporting document provided during the submission of the application. 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.

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

The languages required for the SPC translations are all the official languages of the Union³, Norwegian and Icelandic^{4,5}.

¹ Commission implementing Regulation (EU) No 414/2013

² Commission implementing Regulation (EU) No 354/2013

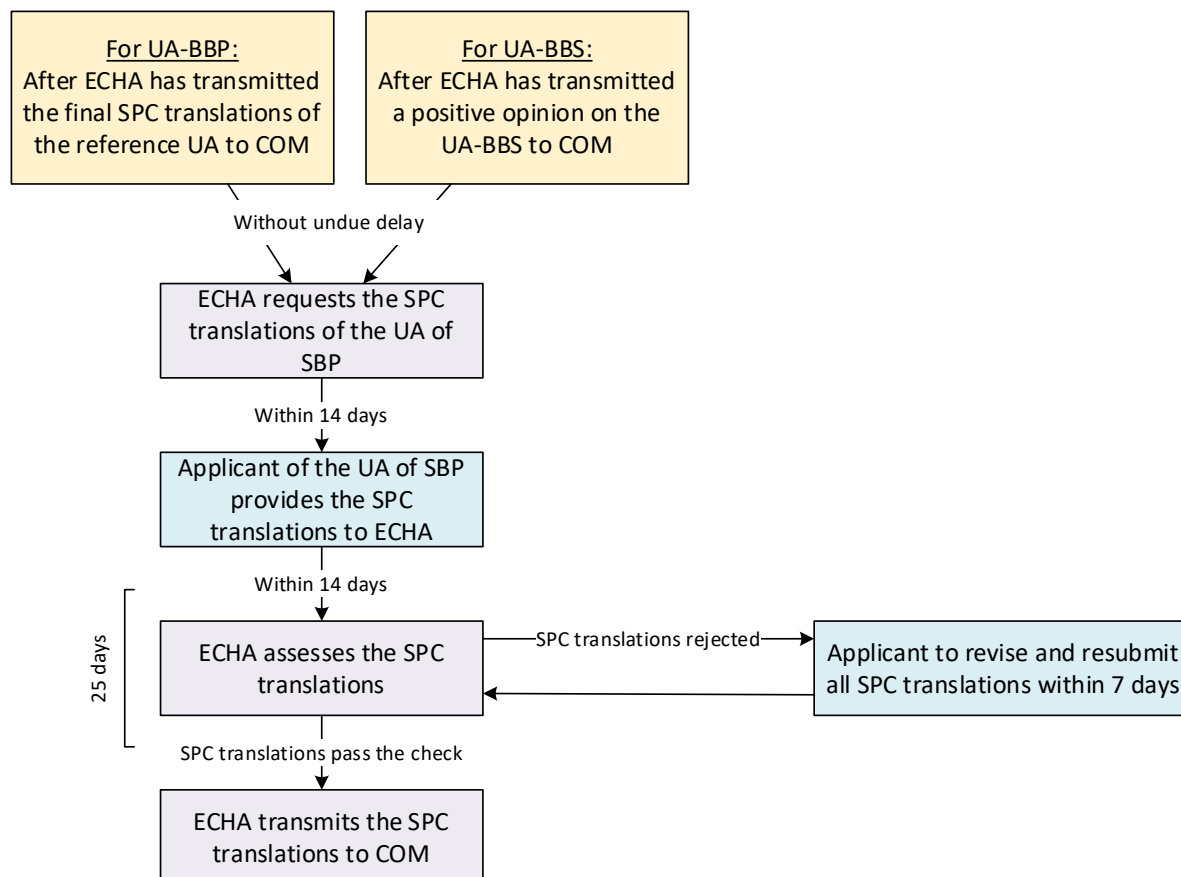
³ Irish is an official language of the EU. Since the derogation from the Council Regulation (EC) 920/2005 is phased out, the SPCs should be translated in Irish too as from 1 January 2021.

⁴ Article 20(3) of the BPR and Chapter XV of Annex II to the EEA agreement.

⁵ Since Icelandic is not included in the languages offered in the SPC editor, it is recommended to use the English SPC template for the Icelandic translation, i.e. the headings will remain in English, and the contents are filled in Icelandic.

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

Figure 1. Flowchart of the linguistic check process of UA applications of SBP



The steps and the relevant deadlines for the check of the SPC translations of UA applications of SBP are listed below. The durations are given in calendar days.

Step	Linguistic check of SPC translations	Responsible actor and deadline
1.	Submission of translation	
	<p><u>For UA applications of SBP of pending UA (UA-BBP):</u></p> <p>After the linguistic review of the SPC translations of the related reference UA application is completed and the final translations have been transmitted to the COM (i.e. Step 4 of the procedure for the linguistic review of the SPC translations for UA applications), ECHA requests the SPC translations of the UA application of SBP from the applicant via an ad hoc communication in R4BP 3.</p> <p><u>For UA applications of SBP of authorised UA (UA-BBS):</u></p> <p>After ECHA has transmitted a positive opinion to COM, ECHA requests the SPC translations of the UA application of SBP from the applicant via an ad hoc communication in R4BP 3.</p>	<p>ECHA</p> <p>Without undue delay</p>
	<p>The applicant provides the SPC translations in xml format to ECHA via an ad hoc communication in R4BP 3 within the given deadline.</p> <p>The translations of the sections of the SPC 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>Applicant</p> <p>Within 14 days</p>
2.	Check	
	<p>ECHA assesses whether the translations of the sections of the SPC not affected by administrative changes are identical to the translations of the SPC of the related reference UA application.</p> <p>If any of the translations is not identical, ECHA will return all SPC translations to the applicant and request an identical translation by ad hoc communication in R4BP 3 at the latest 14 days after ECHA has received the SPC translations.</p> <p><u>Resubmission of SPC translations (when applicable):</u></p> <p>The applicant will amend the SPC translations and reply by submitting all SPC translations within 7 days to ECHA via an ad hoc communication in R4BP 3.</p> <p>ECHA will reinitiate the check of the SPC translations.</p>	<p>ECHA/Applicant</p> <p>25 days</p>

Step	Linguistic check of SPC translations	Responsible actor and deadline
3.	Transmission of final SPC translations	
	ECHA transmits the final SPC translations to COM in xml format via an ad hoc communication in R4BP 3 with the exception of the Norwegian and Icelandic translations. These translations will be transmitted to the relevant MSCA (Norway or Iceland) instead.	ECHA Without undue delay