

Linguistic review of the translations of the summary of product characteristics (SPC) for Union authorisation applications

Version 4.0

Document history

Document history		
Version	Changes	Date
1.0	First edition (original unnumbered version)	16 May 2017
2.0	Provisions regarding the translation of the SPC for SBP authorisations have been added as an Annex Changes in step 2 of the working procedure related to tacit agreement on the translation of the SPC	5 July 2018
3.0	Update on the translation of the SPC in Irish (legal requirement) and Icelandic (footnote)	04 April 2019
4.0	Update on SPC translations process, linguistic check to take place after agreement on the English version of the SPC during the SCBP. Removed information on which MS should check the translation of the English SPC. Provide clarity on the format of the SPC in each step (word or xml format). Additional instructions were added for SPC translations of good and of very poor quality. Clarification on the communication method for ad hoc messages. Improved layout by splitting steps in the table.	17 December 2019

1. Introduction

The Biocidal Products Regulation (BPR) requires the submission of a summary of the product characteristics (SPC) for Union and national authorisations (Article 20). In the case of Union authorisations (UA), the SPC has to be translated in all the official languages of the Union before the authorisation of the product is granted.

According to Article 44(4) of the BPR, ECHA¹ shall transmit to the Commission the translated SPCs within 30 days of submitting the opinion on the authorisation to the Commission. The Article finishes by the words “where applicable” which actually mean that the translation of the draft SPC is only required when the BPC opinion supports granting an authorisation. In this context, the responsible actor for making the translations available to ECHA is the applicant.

In order to ensure the quality of the translations, once the applicant has provided the translations of the SPC, it is essential that Member States (MSs) are involved in the detailed linguistic review of the relevant translation once the Standing Committee on Biocidal Products (SCBP) has agreed on the SPC in English.

A proposal for implementing the provisions of the BPR in relation to preparing and translating the SPC for UA was presented during the Competent authorities (CA) meeting in July 2012 (CA-July12-Doc.5.2.g). Following up on the proposed process, this document outlines a proposal for the working procedure to be followed for the submission and review of the SPC translations by the MSs.

2. Initial considerations and process implementation

Even though the initial submission of the SPC can be done in one of the official languages of the Union accepted by the eCA (Article 20(3)), in the case of UA, it is preferred to submit the SPC in English. This will facilitate the peer-review process by MSs. For the same purpose, it is also recommended to use, to the extent possible, sentences from the glossary of frequently used sentences (when available) for the free text fields in the SPC.

Considering the short timeframe for the submission of the translations, the applicant is strongly advised to initiate the translation process well in advance during the peer review process. This would allow to limit the translation at the end of the peer review phase to the sections or sub-sections updated after the initial translation.

The languages required for the translations are all the official languages of the Union, Norwegian and Icelandic²³.

Irish is an official language of the EU. However, in accordance with the Council Regulation (EC) 920/2005, a derogation applies, following which acts other than Regulations adopted jointly by the European Parliament and the Council do not need to be translated into Irish.

The Commission grants UA by adopting an Implementing Regulation. In line with the above derogation Commission Implementing Regulations and their annexes do not need to be translated into Irish. As SPCs of UA form an annex to the Implementing Regulation, they do not need to be translated in Irish.

Regarding the official languages that are shared by two or more countries, by default, the following MS will be nominated for the checking of the translation:⁴

¹ ECHA is intended in this document as ECHA secretariat.

² Article 20(3) of the BPR and Chapter XV of Annex II to the EEA agreement.

³ 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.

⁴ Where relevant, MSs sharing the same language will collaborate in the review of the translations.

- Dutch: The Netherlands
- French: France
- German: Germany
- Greek: Greece
- Swedish: Sweden

For each UA application, it is possible to derogate from the default nomination, through an agreement between the relevant MS sharing the same official language(s). This should be communicated⁵ at the latest to ECHA before the BPC meeting where the opinion is foreseen to be adopted.

Each MS will appoint a contact person responsible for the coordination within the MS for checking the quality of the translation in the official language(s) of this MS. The actual procedure to follow for the appointment of the contact person is outside the scope of the present document.

The applicant commits to provide good quality translations and to address the MSs comments. In the case of translations considered to be of unacceptably poor quality, the translation will not be accepted and the applicant will have 7 days to amend it. This will result in a delay of the transmission to the Commission of the final translations.

ECHA will be responsible for coordinating the translation review process. The process will be documented using the forms LRUA-F1, LRUA-F2 and LRUA-F3 (See Annexes 1 and 2).

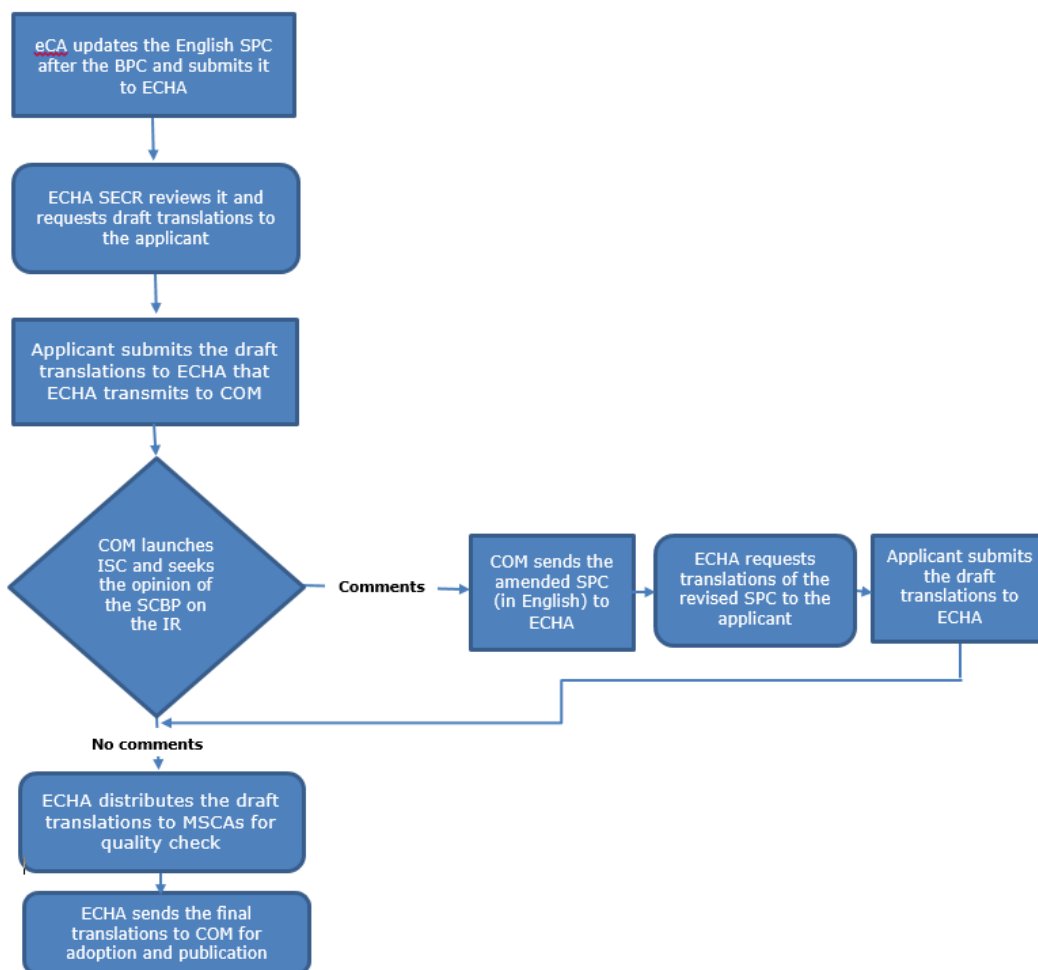
It should be noted that, in the case of a same biocidal product (SBP) application, the SPC of the SBP should be identical to the SPC of the related reference product, with the exception of those sections affected by administrative changes (Articles 3 and 7 of regulation (EU) No 414/2013 and Article 22 of the BPR). Accordingly, it is assumed that the translations of the SPC provided for the SBP application should be identical to those linked to the related reference product (agreement during the CA meeting in March 2018). For SBP applications, the procedure for the review of the SPC translations is outlined in Section 4.

3. Proposed steps for the linguistic review of the SPC translations

The proposed steps and their duration (calendar days) for the review of the SPC translations by the MSs are listed below. Please note that the timelines could be extended when the period falls under holidays, or in case of technical issues hindering the submission of the SPC files in R4BP 3. The procedure will be reviewed in the light of experience.

⁵ The communication should be done via the functional mailbox bpc@echa.europa.eu.

Figure 1: Flowchart of the linguistic review process of Union authorisation applications.



Step	Linguistic review of SPC translations	Responsible actor
1.	Submission of translation	
	The eCA provides via ad hoc communication in R4BP3 the final “master” SPC (xml format, in English). Following the positive opinion of the Biocidal Products Committee, the eCA updates the SPC (xml format) and submits it to ECHA via R4BP3.	eCA
	ECHA SECR cross-checks if the BPC agreements are correctly incorporated and if necessary request resubmission of the SPC without delay. Upon receiving the SPC, ECHA requests the draft translations from the applicant to be submitted to ECHA within 10 days via ad hoc communication in R4BP3 ⁶ .	ECHA (without delay and at the latest when ECHA submits the opinion on authorisation to COM)
	The applicant provides within the deadline the translations (xml format), together with the completed form LRUA-F1 (Section 1) to ECHA via ad hoc communication in R4BP3. ⁷	Applicant (15 days)
	ECHA transmits without delay the translations (word format) to Commission via ad hoc communication in R4BP3.	ECHA
	Commission launches the Inter-service Consultation (ISC) and seeks the opinion of the SCBP on the Implementing Regulation in English language only.	Commission
2.	SPC linguistic review	
	Option 2a: No comments are received during ISC or SCBP ECHA distributes without delay the draft translations (xml format) to MSCAs for linguistic review, together with the form LRUA-F1 via ad hoc communication in R4BP3. The MSCAs should provide the translations (xml format) and the completed LRUA-F1 form (Section 2) within the deadline (details on linguistic review in step 3).	ECHA MSCA (23 days)
	Option 2b: Comments are received during ISC or SCBP Commission sends the amended SPC (word format, in English) to ECHA via ad hoc communication in R4BP3. ECHA requests translations of the revised SPC to the applicant via ad hoc communication in R4BP3. The applicant should provide the translations (xml format) to ECHA within the deadline.	Commission ECHA Applicant (3-5 days)

⁶ To avoid that two weekends are included in the 10 days, the request should be sent on a Monday or Tuesday.

⁷ Given the short timelines for the translation review, the applicant can submit a translated draft SPC to ECHA in reply to the ad hoc communication initiated by ECHA before the submission of the BPC opinion of ECHA to COM.

Step	Linguistic review of SPC translations	Responsible actor
	ECHA distributes without delay the draft translations (xml format) to MSCAs for linguistic review, together with the form LRUA-F1 via ad hoc communication in R4BP3. The MSCAs should provide the translations (xml format) and the completed LRUA-F1 form (Section 2) within the deadline (details on linguistic review in step 3).	ECHA MSCAs (23 days)
3.	<p>Review</p> <p><i>Translation quality check:</i></p> <p>MSCAs perform the detailed linguistic review of the translations.</p> <p>Each translation considered unacceptable will be returned to the applicant by the MSCA nominated for checking this translation at the latest 5 days after receiving the translations. The MSCA will include the form LRUA-F1 with an explanation in Section 2.</p> <p>In case the translated SPC is of such poor quality that it can't be checked, the MS may consider to only return the form LRUA-F1 to the applicant, containing instructions for providing an improved translation of the SPC.</p> <p>The communication will be via ad hoc communication in R4BP3 by selecting the click box "reply required". ECHA should be in cc of the message as this may result in delaying the finalisation of the translation check.</p> <p>In case a translation is provided by the applicant where the MSCA has no comments at all, the MSCA will send the completed, definitive LRUA-F1 form (Section 2) to ECHA via ad hoc communication in R4BP3.</p> <p><i>Resubmission of translation (when applicable):</i></p> <p>The applicant will reply by submitting the amended translation within 7 days to the MSCA who has initiated the ad hoc communication.⁸</p> <p><i>Detailed review of translation:</i></p> <p>MSCAs review the translation and correct the SPC file using the SPC Editor tool.⁹</p> <p>MSCA should make sure that the xml file is (i) for the correct market area: European Union and (ii) that all fields have been filled in correctly : there are no red exclamation marks (▲) in the SPC editor.</p> <p>The MSCA will send the final SPC file (xml format) and the completed, definitive LRUA-F1 form to the applicant and ECHA via ad hoc communication in R4BP3.</p>	MSCAs/Applicant (23 days)

⁸ For the exceptional case where the translations are unacceptable, the total timeline will be extended by 10 days.

⁹ The SPC Editor includes a function that allows the comparison of two SPC files to track the differences between the two files.

Step	Linguistic review of SPC translations	Responsible actor
4.	Transmission of final translations	
	<p>The prerequisite for sending the final translations to the Commission is that each nominated MSCA has provided ECHA with a revised translation or written confirmation that the translation as provided by the applicant is correct. ECHA transmits all final language versions (xml and word format) to COM via ad hoc communication in R4BP3 and uploads the completed form LRUA-F2 in R4BP3.¹⁰</p>	<p>ECHA (2 days)</p>

¹⁰ ECHA will not send the Norwegian and Icelandic translations to the Commission. These translations will be used directly by the relevant MSCA (Norway or Iceland).

4. Proposed steps for the linguistic review of the SPC translations of SBP applications

The proposed steps and their duration (calendar days) for the review of the SPC translations of SBP applications are listed below. Please note that the timelines could be extended when the period falls under holidays, or in case of technical issues hindering the submission of the SPC files in R4BP 3. The procedure will be reviewed in the light of experience.

Step	Linguistic review of SPC translations	Responsible actor
1.	Submission of translation	
	On the day of the submission of the opinion by ECHA to the Commission, ECHA requests the translations of the SPC to the applicant via ad hoc communication in R4BP3. The request should include the deadline for providing the translations (5 days after the submission of the opinion).	ECHA (On the day that ECHA submits the opinion on authorisation to COM)
	The applicant provides within the deadline the translations in xml format to ECHA via ad hoc communication in R4BP 3. The translations of the sections of the SPC not affected by administrative changes should be identical to those of the related reference product.	Applicant (5 days)
2.	Review	
	<p>ECHA checks 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 product. If the translations are not identical, ECHA will return the translation to the applicant and request an identical translation by ad hoc communication in R4BP3.</p> <p><i>Resubmission of translation (when applicable):</i></p> <p>The applicant will reply by submitting the amended translations within 7 days to ECHA by ad hoc communication in R4BP3. ECHA will reinstate the review of the translations.¹¹</p> <p>On day 12 (at the latest) ECHA distributes the translations in xml format to MSCAs via ad hoc communication in R4BP3 with a reply required by day 28. ECHA will indicate the sections affected by administrative changes.</p>	ECHA/Applicant (12 days)

¹¹ For the exceptional case where the translations are unacceptable, the total timeline will be extended by 14 days.

Step	Linguistic review of SPC translations	Responsible actor
	<p>MSCAs review the translation of the sections affected by administrative changes and correct the SPC file using the SPC Editor tool.⁹ MSCAs will consult with the applicant where necessary.</p> <p>MSCA should make sure that the xml file is (i) for the correct market area: European Union and (ii) that all fields have been filled in correctly : there are no red exclamation marks (⚠) in the SPC editor.</p> <p>The MSCA will send the final SPC file in xml format to ECHA and the applicant via ad hoc communication in R4BP3 by day 28.</p>	<p>MSCAs/Applicant (11 days)</p>
3.	Sending of final translations	
	<p>ECHA transmits the final translations to COM (xml and word format) via ad hoc communication in R4BP3 and uploads the completed form LRUA-F3 in R4BP3.¹⁰</p>	<p>ECHA (2 days)</p>

Annex 1: LRUA-Form 1
LRUA-F1
For Member States when performing the linguistic review of the translations

Applicant to complete Section 1 and to send to ECHA by Day 15 after the Opinion is submitted to the Commission

For unacceptable translations: (MS to complete Section 2 and to send to the applicant by day 8 after receiving this document from ECHA)

MS to complete Section 2 and to send to ECHA and the applicant by Day 23 after receiving this document from ECHA¹²

SECTION 1:

Application Details (to be completed by the applicant)

Product Name:

Case number (R4BP 3 reference):

Applicant name and address:

Details of contact person for translations:

Name	
Telephone	
e-mail	
Fax	

SECTION 2:

SPC translation check (to be completed by Member States)

Language:

BG	CS	DA	DE	EL	EN	ES	ET	FI	FR	GA	HR	NO
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HU	IT	LT	LV	MT	NL	PL	PT	RO	SK	SL	SV	IS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

MS performing the linguistic review:

¹² Translations in Norwegian and Icelandic do not need to be forwarded to ECHA.

Contact details of MS :

Contact person	
Telephone	
e-mail	

Overall quality of translation:

VG	G	A	UN*
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(VG=Very Good; G=Good; A=Acceptable; Un=Unacceptable)

*If unacceptable, return translation **within 5 days** to the applicant (copy Agency) and include an explanation in the box below.

The translation was unacceptable because:

Nature of corrections (to be completed after the review):
Major discrepancies
Missing words or sentences
Scientific incorrect translations (e.g. terminology)

Inaccuracies (Incorrect translations – incl. spelling, punctuation, grammatical mistakes)

Editorial, Stylistic changes (e.g. rephrasing)

	M	S	F
Major discrepancies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Missing words or sentences	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Scientific incorrect translations (e.g. terminology)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Inaccuracies (Incorrect translations – incl. spelling, punctuation, grammatical mistakes)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Editorial, Stylistic changes (e.g. rephrasing)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(M=Many; S=Several; F=Few)

Any other comments (e.g. formatting problems, market area problems, empty or incorrect filled fields):

Date of completion of form:

Annex 2: LRUA-Form 2
LRUA-F2
For ECHA when transmitting the translations to Commission

(ECHA to complete when sending the final translations to COM and to upload to the relevant case in R4BP3) - Only one form to be completed for all languages

Product Name:

Case number (R4BP 3 reference):

Applicant name and address:

Overview of the linguistic review of the translations

BG	CS	DA	DE	EL	EN	ES	ET	FI	FR	GA	HR
✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>
x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>
HU	IT	LT	LV	MT	NL	PL	PT	RO	SK	SL	SV
✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>
x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>	x <input type="checkbox"/>

Tick the appropriate box for each language as follows:

✓ LRUA-F1 completed

x LRUA-F1 not provided or provided but not completed

Delay in Member States review? If yes, provide country name and number of days delayed:

Delay in transmitting translations to the Commission? If yes, provide details below:

Any other feedback?

Date: _____ **Review agent:** _____

Annex 3: LRUA-Form 3
LRUA-F3
For ECHA when transmitting the revised translations to Commission of SBP applications

(ECHA to complete by Day 30 after the opinion is submitted to the Commission and to upload to the relevant case in R4BP3) - Only one form to be completed for all languages

Product Name:

Case number (R4BP 3 reference):

Applicant name and address:

Overview of the linguistic review of the translations

BG	CS	DA	DE	EL	EN	ES	ET	FI	FR	GA	HR
✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>
HU	IT	LT	LV	MT	NL	PL	PT	RO	SK	SL	SV
✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>

✓ Translation available and identical to that of the related reference product (with the exception of sections affected by administrative changes)

BG	CS	DA	DE	EL	EN	ES	ET	FI	FR	GA	HR
✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>
HU	IT	LT	LV	MT	NL	PL	PT	RO	SK	SL	SV
✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>	✓ <input type="checkbox"/>

✓ Final SPC from MS received of sections affected by administrative changes.

Remarks

Date: _____ **Review agent:** _____