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

Version 3.0

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

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, ECHA[1] 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 before ECHA transmits these to the Commission.

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 Icelandic[2][3].

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

[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.

following MS will be nominated for the checking of the translation:[4]

- Dutch: The Netherlands
- English: United Kingdom
- 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 communicated[5] 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).

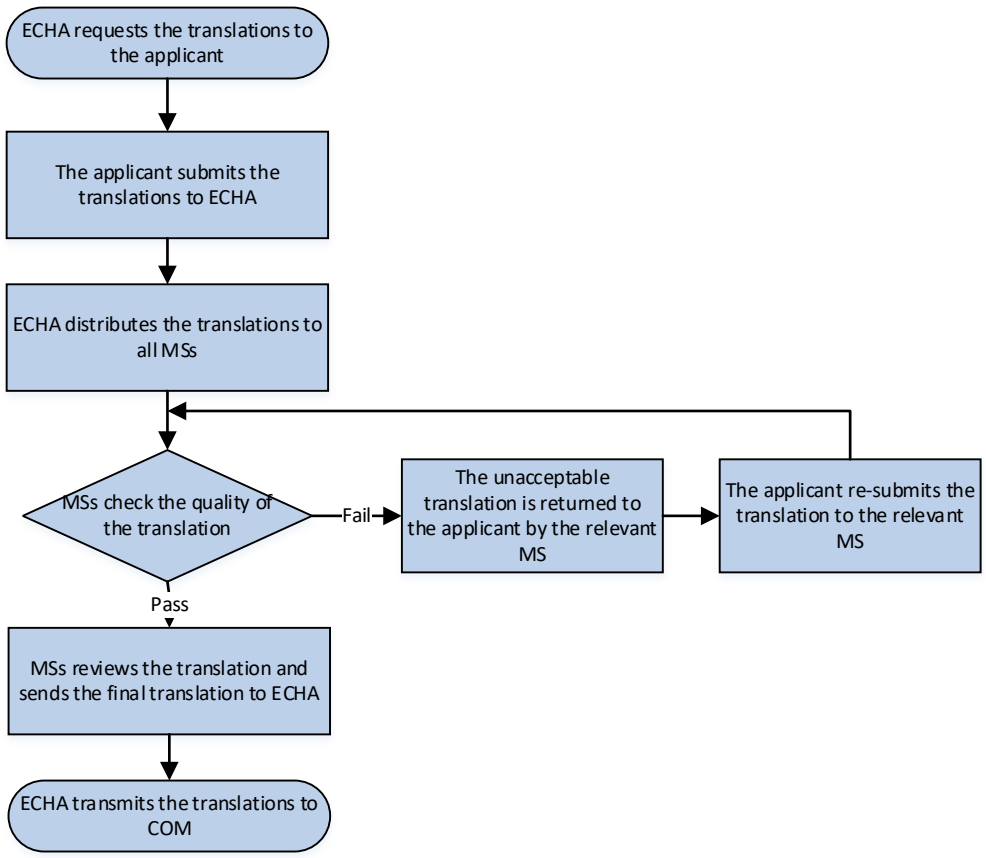
It should be noted that, in the case of a same biocidal product (SBP) application, the SPC of the SBP should be identical to the SPC of the related reference product, with the exception of those sections affected by administrative changes (Articles 3 and 7 of regulation (EU) No 414/2013 and Article 22 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 takes into consideration previous experience gained by the European Medical Agency (EMA) in a similar process for the authorisation of medicinal products. The procedure will be reviewed in the light of experience.

[4] Where relevant, MSs sharing the same language will collaborate in the review of the translations.
[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** As soon as the final "master" SPC is provided by the eCA and at the latest on the day of the submission of the opinion by ECHA to the Commission, ECHA sends the final "master" SPC and requests the translations of the SPC to the applicant via ad hoc communication in R4BP 3. The request should include the deadline for providing the translations (5 days after the submission of the opinion[6]). The applicant provides within the deadline the translations in xml format, together with the completed form LRUA-F1 (Section 1) to ECHA via ad hoc communication in R4BP 3.[7] ECHA distributes without delay the translations for the detailed linguistic review via ad hoc communication with reply required in R4BP 3 with a deadline of 23 days.	**ECHA** (without delay and at the latest when ECHA submits the opinion on authorisation to COM) **Applicant** (5 days) **ECHA** (without delay)
2.	**Review** MSs perform the detailed linguistic review of the translations. *Translation quality check:* Each translation considered unacceptable will be returned to the applicant by the MSCA nominated for checking this translation at the latest 3 days after receiving the translations. The MSCA will include the form LRUA-F1 with an explanation in Section 2. The communication will be via ad hoc communication in R4BP 3 by selecting the click box "reply required". In parallel, the MSCA informs without delay ECHA of the non-acceptance of the translation via ad hoc communication as this may result in delaying the finalisation of the translation check. *Resubmission of translation (when applicable):* The applicant will reply by submitting the amended translation within 7 days to the MSCA who has initiated the ad hoc communication.[8] *Detailed review of translation:* MSs review the translation and correct the SPC file using the SPC Editor tool.[9] The MSCA will send the final SPC file in xml format and the completed LRUA-F1 form to the applicant and ECHA via ad hoc communication in R4BP 3.	**MSs / Applicant** (23 days)

[6] Where possible, the submission will not happen on Fridays.
[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.
[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
3.	**Sending of final translations** The prerequisite for sending the final translations to the Commission is that each nominated MS has provided ECHA with a revised translation or written confirmation that the translation as provided by the applicant is correct and that no further comments will be submitted at a later stage (i.e. SC level). ECHA transmits the final translations to COM via ad hoc communication in R4BP 3 and uploads the completed form LRUA-F2 in R4BP 3.[10]	**ECHA** (2 days)

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 R4BP 3. The request should include the deadline for providing the translations (5 days after the submission of the opinion). 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.	**ECHA** (On the day that ECHA submits the opinion on authorisation to COM) **Applicant** (5 days)

[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).

Step	Linguistic review of SPC translations	Responsible actor
2.	**Review** 1) 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. *Resubmission of translation (when applicable):* The applicant will reply by submitting the amended translations within 7 days to ECHA by ad hoc communication in R4BP3. ECHA will reinitiate the review of the translations.[11] On day 12 (at the latest) ECHA distributes the translations to MSs via ad hoc communication in R4BP 3 with a reply required by day 28. ECHA will indicate the sections affected by administrative changes. 2) MSs review the translation of the sections affected by administrative changes and correct the SPC file using the SPC Editor tool.[9] MSs will consult with the applicant where necessary. The MSCA will send the final SPC file in xml format to ECHA and the applicant via ad hoc communication in R4BP 3 by day 28.	**ECHA / Applicant** (12 days) **MSs / Applicant** (11 days)
3.	**Sending of final translations** ECHA transmits the final translations to COM via ad hoc communication in R4BP 3 and uploads the completed form LRUA-F3 in R4BP 3.[10]	**ECHA** (2 days)

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

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 5 after the Opinion is submitted to the Commission)
(MS to complete Section 2 and to send to ECHA and the applicant by Day 28 after the Opinion is submitted to the Commission)[12]
For unacceptable translations: (MS to complete Section 2 and to send to the applicant by day 8 after the Opinion is submitted to the Commission)

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
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	HU	IT	LT	LV	MT	NL	PL	PT	RO	SK	SL	SV	IS
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

MS performing the linguistic review:	

[12] Translations in Norwegian and Islandic 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*
☐	☐	☐	☐

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

***** If unacceptable, return translation **within 3 days** to the applicant (copy Agency) and include and explanation in the box below.

The translation was unacceptable because:

Nature of corrections (to be completed after the review):

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

Any other comments (e.g. formatting problems):

Date of completion of form:

Annex 2: LRUA-Form 2

LRUA-F2

For ECHA when transmitting the revised translations to Commission

(ECHA to complete by Day 30 after the opinion is submitted to the Commission and to upload to the relevant case in R4BP 3) - 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
✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐
x ☐	**x** ☐	**x** ☐	**x** ☐	**x** ☐	**x** ☐	**x** ☐	**x** ☐	**x** ☐	**x** ☐	**x** ☐	**x** ☐
HU	**IT**	**LT**	**LV**	**MT**	**NL**	**PL**	**PT**	**RO**	**SK**	**SL**	**SV**
✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐
x ☐	**x** ☐	**x** ☐	**x** ☐	**x** ☐	**x** ☐	**x** ☐	**x** ☐	**x** ☐	**x** ☐	**x** ☐	**x** ☐

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 R4BP 3) - 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
✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐
HU	**IT**	**LT**	**LV**	**MT**	**NL**	**PL**	**PT**	**RO**	**SK**	**SL**	**SV**
✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐

✓ 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
✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐
HU	**IT**	**LT**	**LV**	**MT**	**NL**	**PL**	**PT**	**RO**	**SK**	**SL**	**SV**
✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐	✓ ☐

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

Remarks

Date: _____ **Review agent:** _____