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

Version 6

Until the SPC in IUCLID (.i6z format) is launched, the SPCs should be prepared in .xml format using the SPC Editor tool.

Document history

Document history			
Version	**Changes**	**Date**	**Date of applicability[1]**
1.0	First edition (original unnumbered version)	16 May 2017	28 July 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	24 July 2018
3.0	Update on the translation of the SPC in Irish (legal requirement) and Icelandic (footnote)	04 April 2019	11 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 lay out by splitting steps in the table.	17 December 2019	18 December 2019
5.0	Update on the translations of the SPC in Irish (legal requirement). Removing the part in relation to the same biocidal products in a separate document. Other editorial changes are implemented.	7 September 2022	13 September 2022
5.1.	Extending deadline for the applicant to provide the revised translations of the SPC and SPC in English after the SCBP (see step 2, option 2b).	22 November 2022 (BPC-45)	30 November 2022
6	Changes incorporated: • to address major changes application process, • implementation of the SPC in IUCLID,	Agreement date: 49-BPC 22 November 2023	5 December 2023

[1] This is the date when the document is published on ECHA website.

	• inclusion of the date of applicability, • adding step 5, • making some editorial changes.		

1. Introduction

The Biocidal Products Regulation[2] (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[3] shall transmit to the Commission (the COM) the translated draft SPCs within 30 days of submitting the opinion on the authorisation to the COM. The Article finishes by the words "where applicable" which is interpreted as meaning that the translation of the draft SPC is only required when the BPC opinion supports granting an authorisation.

According to Article 13(8) of the Changes regulation[4], ECHA shall transmit to the COM the translated draft revised SPC within 30 days of submitting the opinion on the revision of the authorisation to the COM. The Article refers to the words "where relevant" which is interpreted as meaning where the SPC needs to be amended based on the outcome of the assessment of the changes application.

In this context, the responsible actor for making the translations available to ECHA is the applicant[5].

In order to ensure the quality of the translations, once the applicant has provided the draft[6] translations of the SPC, it is essential that Member States (MSs) are involved in the detailed linguistic review of the relevant translation after the Commission is providing the amended SPC in English:

- for UAs after the Standing Committee on Biocidal Products (SCBP) has agreed on the SPC in English,
- for major changes of the UA (UA-MAC) after the Commission InterService Consultation (ISC)[7].

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 for Union authorisation applications by the MSs. A similar approach is proposed to be followed for the submission and review of the SPC translations for UA-MAC[8].

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[9], in the case of UA and UA-MAC, it is recommended to submit the SPC in English. This will facilitate the opinion forming and decision making process by MSs and the Commission. For the same purpose, it is also recommended to use sentences from the glossary of frequently used sentences (when available) for the free

[2] Biocidal Products Regulation (EU) No 528/2012 of the European Parliament and of the Council.
[3] ECHA is intended in this document as ECHA secretariat.
[4] Commission Implementing regulation (EU) No 354/2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the Eruopean Parliament and of the Council.
[5] Article 20(3) of the BPR for UA, Article 13(7) of Changes Regualtion for UA-MAC
[6] In the context of UA-MAC this should be read as the *revised* draft translations. This approach is applicable throughout the document.
[7] The SCBP is not consulted on applications for changes to Union authorisations - Article 50(2) of the BPR.
[8] Only difference for the UA-MAC is that the SPC in English provided by the COM is not voted in the SCBP.
[9] For UA applications - Article 20(3) of the BPR, for UA-MAC – Article 5(1)(e)(2) of the Changes regulation.

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 opinion forming process. This would allow to limit the translation at the end of the opinion forming 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[10], Norwegian and Icelandic[11]. However, the Commission is not using the Norwegian and Icelandic versions of the SPC during the finalisation of the decision making process. Those versions are managed by the Norwegian and Icelandic authorities to finalise their decisions.

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:[12]

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

For each UA or UA-MAC 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[13] 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[14] and to address the MSs' comments. In the case of translations considered to be of unacceptably poor quality, the translation will be rejected and the applicant will have 7 days to provide good quality translations. This will result in a delay of the transmission to the COM of the final translations.

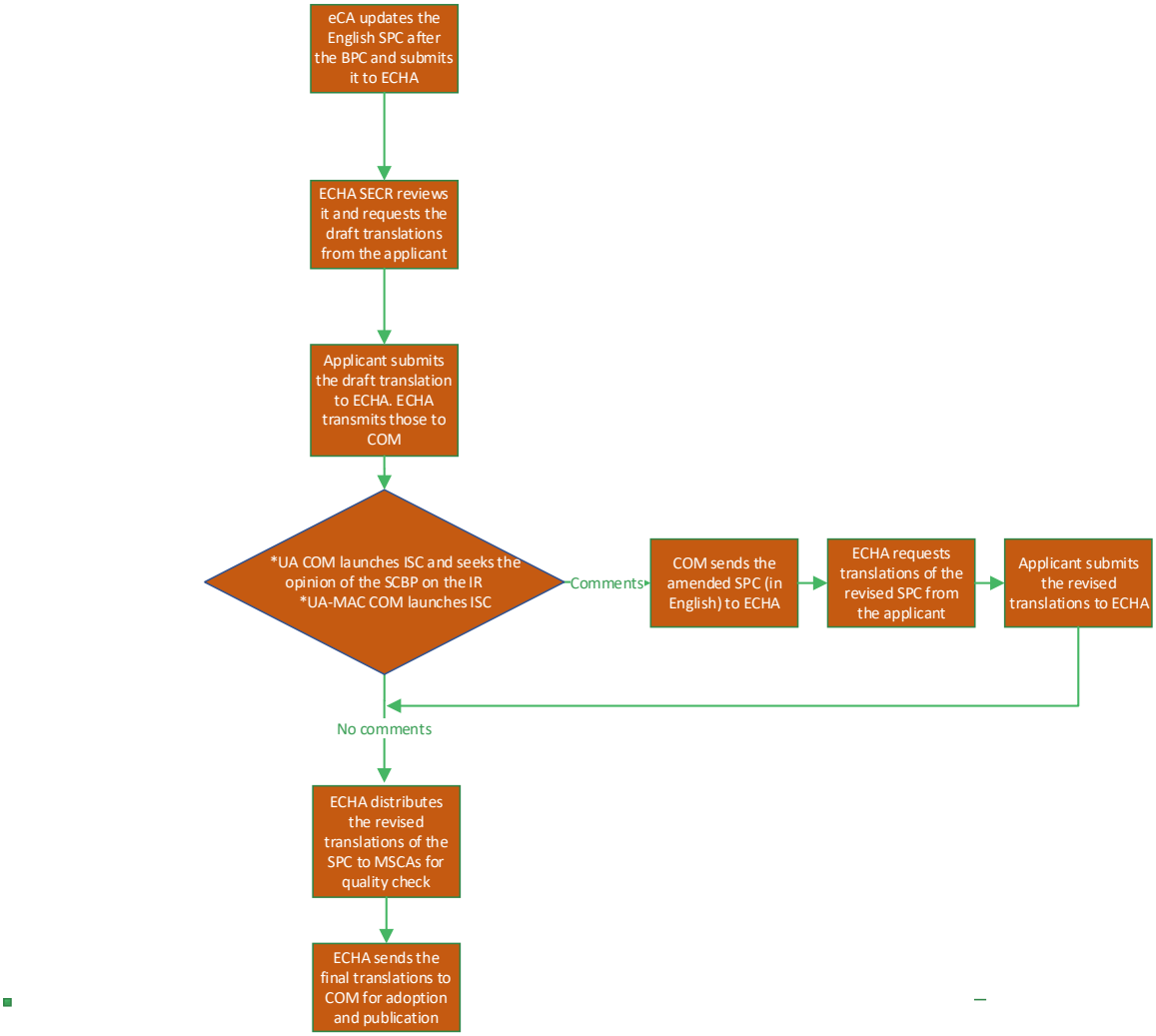
ECHA will be responsible for the administrative coordination of the translation review process. The process will be documented using the forms LRUA-F1 and LRUA-F2 (see Annexes 1 and 2).

3. 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. The procedure will be reviewed in light of experiences gained.

[10] 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.
[11] Article 20(3) of the BPR and Chapter XV of Annex II to the EEA agreement.
[12] Where relevant, MSs sharing the same language will collaborate in the review of the translations.
[13] The communication should be done via the functional mailbox bpc@echa.europa.eu.
[14] Please see also the Summary of product characteristics (SPC) - quality checklist.

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



Step	Linguistic review of SPC translations	Responsible actor and deadlines
1.	**Submission of translation**	
	The eCA provides via ad hoc communication in R4BP 3 the final "master" SPC (i6z format, in English). Following the positive opinion of the Biocidal Products Committee (BPC), the eCA updates the SPC (i6z format) and submits it to ECHA via R4BP3[15].	**eCA**
	ECHA SECR cross-checks if the BPC agreements are correctly incorporated and if necessary request resubmission of the SPC from the eCA.	**ECHA** (without undue delay)
	ECHA requests the draft translations from the applicant, to be submitted to ECHA, via ad hoc communication in R4BP 3.	**ECHA** (in the next working day after ECHA submits the opinion on authorisation to COM)
	The applicant provides within the deadline the draft translations (i6z format), together with the completed form LRUA-F1 (Section 1) to ECHA via ad hoc communication in R4BP 3.	**Applicant** (15 days)
	ECHA transmits the draft translations (by referring to the communication where the applicant provides SPC translations) to the COM via ad hoc communication in R4BP 3[16].	**ECHA** (without undue delay)
	For UA applications - the COM launches the InterService Consultation (ISC) and seeks the opinion of the SCBP on the Implementing Regulation in English language only. For UA-MAC applications - the COM launches the InterService Consultation (ISC).	**The COM**
2.	**SPC linguistic review**	
	Option 2a: No comments are received during ISC or SCBP After confirmation from the COM, ECHA distributes the draft translations (i6z format) to MSCAs for linguistic review, together with the form LRUA-F1 via ad hoc communication in R4BP3[17]. The MSCAs should provide the translations (i6z format) and the completed LRUA-F1 form (Section 2) within the deadline (see details on linguistic review in step 3).	**ECHA** (without undue delay) **MSCA** (23 days)

[15] For this step deadlines are set via the Timelines for the opinion forming process of Union Authorisation and via the Timelines for the opinion forming of union auhtorisation major changes applications. The documents are available in ECHA website: LINK.
[16] Article 44(4) of the BPR
[17] The applicant will be in cc of this communication in R4BP3.

Step	Linguistic review of SPC translations	Responsible actor and deadlines
	Option 2b: Comments are received during ISC or SCBP The COM sends the amended SPC in track change mode (word format, in English), as agreed by SCBP (for UA) or as agreed after the ISC consultation (UA-MAC), to ECHA via ad hoc communication in R4BP 3. ECHA requests to update the translations of the revised SPC to the applicant via ad hoc communication in R4BP 3. The applicant should provide the revised translations and updated English SPC (i6z format) to ECHA within the deadline.	**COM** **ECHA** **Applicant** (14 days)
	ECHA distributes the revised translations and updated English SPC (i6z format) (by referring to the communication where the applicant provides SPCs) to MSCAs for linguistic review, together with the form LRUA-F1 via ad hoc communication in R4BP 3[18]. The MSCAs should provide the translations (i6z format) and the completed LRUA-F1 form (Section 2) within the deadline (see details on linguistic review **in step 3**).	**ECHA** (without undue delay)[19] **MSCAs** (23 days)
3.	**Review - translation quality check**	
	MSCAs perform the detailed linguistic review of the translations. ***<u>If translations are considered unacceptable or of poor quality:</u>*** 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 via ad hoc communication in R4BP3 (include ECHA in cc of the ad hoc communication). The MSCA will include the form LRUA-F1 with an explanation in Section 2. 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. The applicant should be informed via ad hoc communication in R4BP 3 by selecting the click box "reply required". The MSCA should set the deadline for the applicant. ECHA should be in cc of the message as this may result in delaying the finalisation of the translation check.	**MSs/Applicant** (23 days)

[18] The applicant will be in copy of this communication in R4BP3.
[19] If possible, those should be sent out on the first working days of the week, i.e., by Wednesday.

Step	Linguistic review of SPC translations	Responsible actor and deadlines
	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.[20] *Detailed review of the resubmitted translation:* MSCAs review the translation and correct the SPC file.[21] MSCA should make sure that the i6z file is (i) for the correct market area: European Union and (ii) that all fields have been filled in correctly. The MSCA will send the final SPC file (i6z format) and the completed, definitive LRUA-F1 form to the applicant and ECHA via ad hoc communication in R4BP 3. ***<u>If translations are considered acceptable:</u>*** In case a translation is provided by the applicant where the MSCA has no comments, the MSCA will send the completed, definitive LRUA-F1 form (Section 2) to ECHA via ad hoc communication in R4BP3.	
4.	**Transmission of final translations**	
	ECHA transmits the final translations (i6z format) to the COM via ad hoc communication in R4BP 3 and uploads the completed form LRUA-F2 in R4BP 3.[22] If MSCA does not provide a revised translation or written confirmation that the translation as provided by the applicant is correct, ECHA informs the COM and transmits the translations as provided by the applicant.	**ECHA** (without undue delay)
5.	If during the publication process, the Publication Office still discovers discrepancies between the Word linguistic versions of the SPC, the COM will request the applicant to align the i6z versions of the SPC to the text of the published SPCs. The objective is to keep in R4BP a version of the SPC identical to the one published in the EU Official Journal.	**COM**

[20] For the exceptional case where the translations are unacceptable, the MS can extend the timeline for the applicant by 3 additional days. However, the linguistic review of the translations by MSs need to be finalised by day 23.
[21] The SPC in IUCLID includes a function that allows the comparison of two SPC files to track the differences between the two files.
[22] ECHA will not send the Norwegian and Icelandic translations to the COM. These translations will be used directly by the relevant MSCA (Norway or Iceland).

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).
MS to complete Section 2 and to send to ECHA and the applicant by day 23 after receiving this document from ECHA[23]

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:	

[23] 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)

The translation was unacceptable because:

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

	M	S	F	Description*
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)

*MS might use this column if would like to provide more detailed feedback on the nature of corrections.

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

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 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: _____ **ECHA Secretariat**