

Guide to translating the Summary of Product Characteristics, SPC

Introduction

For products brought to market under the Biocidal Product Regulation (EU) 528/2012 (BPR), the Summary of Product Characteristics (SPC) is a fundamental part of the authorization. The SPC contains the authorized product names, instruction for first-aid and use, classification and more.

Biocidal Product Families (BPF) are summarized in SPCs as collections of MetaSPCs, which follow the same format as single biocidal products.

The essential information needed to create product labels and use instructions can always be found in the SPC, and member states may require a translation of the agreed upon master SPC, which is often in English. In Denmark, the SPC used for the final authorization of a biocidal product must be translated to Danish, as per BPR Article 20(1)(a)(ii).

ECHA provides general guidance for preparing an SPC with a BPR application: [SPC Editor - ECHA \(europa.eu\)](#)

During evaluation and risk assessment, involved member states will discuss and agree upon a final English SPC to be authorized, and it is this master SPC that must be translated.

How to translate the SPC

It is the responsibility of the applicant to create a high quality SPC translation from the master SPC file. This guide is valid for all languages, but the specific examples relate to a Danish language translation.

SPC files have the .i6z extension and must be opened in IUCLID for editing. Since Feb 12th 2024, the former .XML format is no longer valid, and all SPC-files are now created and edited using IUCLID.

IUCLID (International Uniform Chemical Information Database) is a software package developed by ECHA and OECD, which relies on OECD Harmonized Templates (OHTs) to record and view data about chemicals. Applications for product applications under the BPR have long been accompanied by a IUCLID dossier containing all relevant data to be used in the assessment of the product. This means that the same dataset which is used to generate the dossier that accompanies an application may also be used to generate the draft SPC. IUCLID is under active development and there are several options for maintaining a IUCLID dataset, including cloud access which is always up to date. You can read more about the IUCLID project here, as well as download servers and clients: [Home - IUCLID \(europa.eu\)](#)

The SPC Editor is a specific Working Context when viewing a chemical dataset in IUCLID.

1. With the master dataset open in IUCLID, click on the “Working context” button to reveal a drop-down menu. In this menu click the “BPR Summary of product characteristics (SPC)” entry, figure 1.
2. The language context for the SPC is contained in the header, which is the topmost entry in the dossier navigation column on the left, see figure 2. In the header, correct market area and language must be set. This will affect the SPC dossier which can be generated from the dataset.
3. The SPC header does not change the interface language on IUCLID, and it is therefore recommended to align the interface with the header information, to ensure a high quality translation. The interface language can be changed from the dashboard, see figure 3.

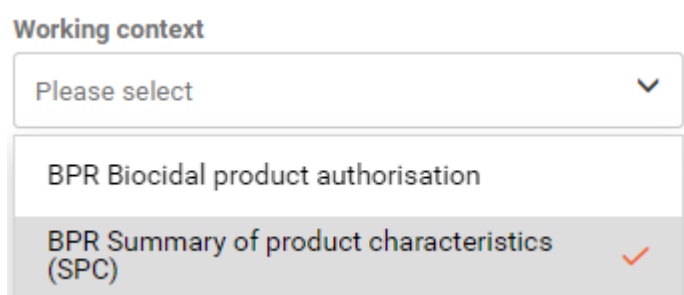


Figure 1 – Correct working context



Figure 2 – Choosing language and market area

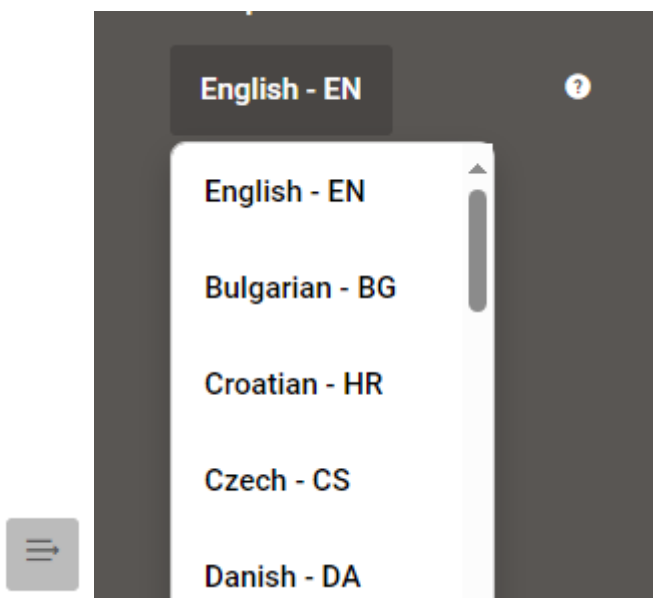


Figure 3 – Choosing interface language from the dashboard

To ensure a high quality translation, please make sure to check the following:

- Most hazard- and precautionary statements are automatically translated by the SPC editor, but some contain free-text fields which must be manually translated. ECHA publishes a small guide to the most important quality checks, which can be found here: [spc_quality_checklist_en.pdf \(europa.eu\)](#)
- Target organisms defined under “Authorised uses” typically have a universal scientific name and a language specific common name, which must be translated to Danish.
- The master SPC may contain sentences that have official translations, known as Frequently Used Sentences. ECHA maintains a public list which can be found here: https://echa.europa.eu/documents/10162/17242/frequently_used_sentences_spc_translations.xls