

# Guide to translating the Summary of Product Characteristics, SPC

## Introduction

For products brought to market under the Biocidal Product Regulation (EU) 582/2012 (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: [c4a70e46-200a-3217-0631-fd08883521cc \(europa.eu\)](https://europe.ec.europa.eu/echa/activities/bpr/summary-product-characteristics)

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 .xml extension and can be opened in most modern browsers for viewing and/or printing. However, to edit or create an SPC, the SPC Editor must be used. The SPC editor<sup>1</sup> is a free online tool provided by ECHA, which can be accessed here: [SPC Editor \(europa.eu\)](https://europe.ec.europa.eu/echa/activities/bpr/summary-product-characteristics)

1. With the master SPC open in the SPC Editor, click on the “New” button to reveal a drop-down menu. In this menu click the “Language version” entry, figure 1.
2. In the pop up dialog (figure 2), make sure to set the Market area to Denmark and the language to Danish. Then click OK and wait for the SPC Editor to generate a new SPC, which will automatically open.
3. The SPC may now be translated and saved to a new .xml file. The default filename for the new SPC should contain DK\_da

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<sup>1</sup> The SPC editor is set to be replaced by a new tool which integrates with IUCLID6 in 2024. The .xml format will remain valid for the time being, but users are encouraged to familiarize themselves with IUCLID6.

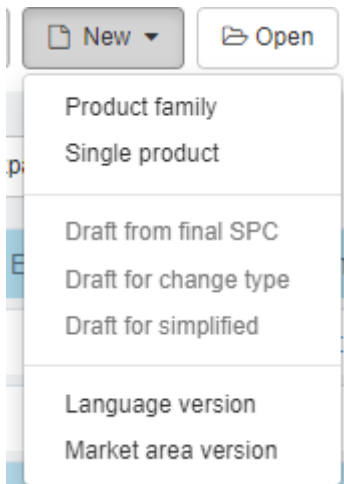


Figure 1 – New language version

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New: Language version


|               |  |
|---------------|--|
| Family UUID   | <input type="text"/>   |
| * Family name | <input type="text"/>  |
| * Market area | <input type="text" value="Denmark"/>   |
| * Language    | <input type="text" value="Danish"/>  |

Figure 2 – Choosing language and market area

To ensure a good 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.
- 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](https://echa.europa.eu/documents/10162/17242/frequently_used_sentences_spc_translations.xls)  
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