



Quality of SPC documents and translations

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EN master SPC – WORD format

- Is used for the regulatory process of the Commission
- High quality standard required for publication in the EU OJ
 - I. The SPC is annexed to a legal act granting an autorisation
 - II. The Commission is responsible for the autorisation (instructions shall be clear for the users)
 - III. Commision style guide for the publication of legal acts

EN master SPC – WORD format

- After reception of the SPC, the Commission will:
 1. Check whether the conclusions of the BPC have been correctly incorporated
 2. Check whether the instructions are clear and unambiguous (ECHA, eCA involved)
 3. Check the compliance of the draft with the drafting recommendations (see next slides)
 4. Submit the draft SPC for revision by the COM legal revisors

EN SPC: the reference SPC – editorial errors

DO NOT	Please DO
Use decimal point : 0.5	Use decimal comma : 0,5
Expression of units : mL, Kg, L	Expression of units : ml, kg, litres
Surface and volume : m ² , m ³	Surface and volume: m ² , m ³
use '/'	Use rather 'and', 'or'
Time units: min, sec, h	Time units: minutes, seconds, hours
use 'should' or 'may'	Use conclusive message: 'need to', 'shall' or 'must'
Use acronyms (e.g. HDPE)	Acronyms shall be explained only when they first appear in the text.
Use words with first capital letter in the middle of sentences (e.g. Healthcare), repetition of words, sentence without verbs	Involve an EN native speaker in the revision of the SPC if possible

EN SPC: the reference SPC : incoherences

DO NOT	Please DO
Describe the market area as DE, BE, NL, IT....	Market area : EU is the only market area accepted for Union authorisations
Leave empty fields in section 4.1	Please make sure that all the fields in the table of section 4.1 – description of use are correctly filled in
Repeat information in the section ‘application methods’ of section 4.1	It is not necessary to repeat under the section ‘detailed description’ the text already indicated for the section ‘method’
Use machine translations	Hire the service of competent translators
Introduce references to EN norm or other EU regulations without explanation	Include the full title of EN norm or EU law when first mention
Make unclear use instructions	Please make sure that the instructions are clear for the users. Please involve a EN native speaker if possible
Send the SPC without a second look !	Check for coherence throughout the text

Linguistic versions of the SPC : most common issues

- During the linguistic review:
- **The EN SPC as voted on by the Member States authorities is binding and final.** No change are allowed in the EN version. The other versions need to be similar to the agreed EN version
- If mistakes, differences are detected after adoption, a corrigenda is required and delays the closure of the asset in R4BP.
- Preparation of corrigenda is a long and resource intensive process. Avoid resorting to this process

Linguistic versions of the SPC : most common issues

Please do not	Please do
Leave untranslated text in an SPC	Ensure that different languages are not mixed up in a SPC
Add additional text compared to the EN SPC reference document (the one agreed by the authorities)	Ensure that each translation is the accurate reflection of the EN master SPC
Remove text compared to the EN SPC reference document	Ensure that each translation is the accurate reflection of the EN master SPC
Leave unnecessary spaces in the documents	Please remove as far as possible unnecessary spaces between paragraphs or sections of the SPCs
Leave missing spaces between words, figures and their units...	Please add spaces where relevant (e.g. after semi-colon, colon or a comma,...)

Actions expected from IT developers

- Expectations regarding the WORD format of the SPCs

Actions expected from IT developers

- Ensure that the wording of Annex III to the CLP is correctly reflected in the SPC Editor under IUCLID (E.g P 501 – Dispose content/container **to** hazardous or special waste collection point **in accordance with** local/regional/national/international regulation)
- Ensure that the composition table contains the correct information:
 1. Correct CAS and EC numbers at least for active substances. Make sure that this information is corrected when mistakes are detected for CoF
 2. Correct IUPAC name (not mixed with the common name)
 3. Releasers are correctly identified as such in the WORD format

Actions expected from IT developers

- Dilution (%) : ‘-’ but not applicable for RTU products. WORD version
- Scientific names of target organisms : removed if unused.
- Development stage: bug ? Xml : no data but in WORD; it stays
- Give the possibility to introduce footnotes everywhere in the xml template under the new IUCLID format
- Ensure that there is powerful comparison tool in the new application (check of empty (or semi empty) fields, check of inappropriate language present in the SPC ?).
- Ensure that the tool populating the WORD SPC with details from R4BP or IUCLID is not affected by the migration of the SPC Editor to IUCLID (direct importation of the names of the authorisation holder, suffix of the meta-SPCs...)

General conclusions

- The new SPC Editor under IUCLID should serve the needs of the legislative drafting
- Flexibility of the tool: not possible to foresee all our needs for the next 5 years

Thank you



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