

WORKING DRAFT

Phase 1

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Structured Product Labelling (SPL) – Validation Related

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Published by authority of the

Minister of Health

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Health Products and Food Branch



DOCUMENT REVISION HISTORY

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# Introduction & General Information

This section will outline the intent of the document.

## Purpose

This document details how the Health Products and Food Branch (HPFB) implements validation of the Structured Product Labeling (SPL) document.

## Inquiries

Questions should be emailed to [hc.hpr-rps.sc@canada.ca](mailto:hc.hpr-rps.sc@canada.ca)

# Validation Limitations

Detailed below are known limitations, they may be addressed in the future.

1. SPL: Schema Validation only identifies the element or attribute that caused the error, but it does not give the line number or xPath.
2. SPL: Errors that cause a schema error are not included in the content validation.
3. SPL: There is no check that all required content sections are present only that the sections that are present are appropriate.
4. SPL: At this time validation is limited to intra element meaning no validation occurs between element content, in the future inter element validation and eventually inter document validation will be added. Examples:
   1. Intra element, checking that the code is in the CV.
   2. Inter element, are all the MPID’s in the performance section represented in the product section
   3. Inter document, is the version number for the setID the next larger integer than the last revision contained in the repository.
5. SPL: At this time the prolog is not validated.
6. SPL: At this time the xml document attributes are not validated.
7. SPL: The telecom element has limited validation at this time.
8. SPL: Validation for categories 10, 12, 13 and 14 is still outstanding.
9. SPL: There is currently no validation for the suffix on the asEntityWithGeneric.name element.
10. SPL: There is currently no validation for para 3,4 or 7 of the quantity element.
11. SPL: There is currently no validation for para 4,5 and 6 of the ingredientSubstance element.
12. SPL: There is currently no validation for para 6,7 and 8 of the asContent element.
13. SPL: There is currently no validation for aspects solely related to devices such as parts, asSpecializedKind, etc…
14. SPL: There is currently no validation for para 9 of the characteristic element, additionally there is currently no check for the number being a positive integer or text content being included in the element.
15. DT: Currently there is no format validation for the effectiveTime value.
16. DT: Currently there is no validation that the Prolog does not contain additional information.
17. DT: Currently there is no validation for the following Labeling Section aspects:
18. Checking that the section is contextually correct
19. Checking that the section inclusion is correct
20. Checking that the there are no omitted sections
21. Checking that the section order is correct
22. Checking that the section nesting is correct
23. Checking that the section cardinality is correct

# Rule Types & Building Blocks

Rules can either be general (apply to all doctypes) or specific to a doctype (or even to a specific template). General rules are identified as SPL rules or even broader as a category rule, while DT rules are specific to a Doctype or Doctype/Template combination.

For both types there can be status constraints that further refine the scope of a validation check.

Rules can be constructed using the following building blocks, in order to determine the severity:

1. Category, this aspect is mandatory and maps to the rule categories detailed below, the HC Validation rules use the flag attribute within the Schematron result file as the link.
2. Doctype, this aspect is optional and allows for a constraint of the applicably, the HC Validation rules use the /document/code[codeSystem=’2.16.840.1.113883.2.20.6.10’]/@code attribute within the SPL document as the link. Note this is the code element from the CV not the name.
3. templateID, this aspect is optional and allows for a constraint of the applicably, the HC Validation rules use the /document/templateId [root =’2.16.840.1.113883.2.20.6.9’]/@extension attribute within the SPL document as the link. Note this is the code element from the CV not the name.
4. Status, this aspect is optional and allows for a constraint of the applicably, the HC Validation rules use the /document/versionNumber/@description attribute within the SPL document as the link. Note this is the code element from the CV not the name.
5. RuleID, this aspect is optional and allows for a specific rule to override the default severity. The HC Validation rules use the id attribute within the Schematron result file as the link.

# Rule Scope

The checks can be very wide or narrowly defined as required where the scope of a rule can be as narrowly defined as a combination of the following characteristics

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Applicability | Category | RuleID | Doctype | templateID | Status |
| Broadest | X |  |  |  |  |
|  |  |  | X |  |  |
|  |  |  | X | X |  |
|  |  |  | X | X | X |
|  |  | X |  |  |  |
|  |  | X | X |  |  |
|  |  | X | X | X |  |
| Narrowest |  | X | X | X | X |

This model allows for the highest level of flexibility in determining the severity.

# Validation Report Outline

There are 3 possible validation reports:

1. Schema Validation Errors, if the validation was terminated due to a schema error the report will include a summery that details what the report is based upon and the details of the schema validation.
2. Invocation Errors, if the validation was terminated due to an invocation error than the report will only the detail what caused the error.
3. Content Checking, if the validation executed content checks than the report will include a summery that details what the report is based upon, the details of the schema validation as well as details for the content checks.

The validation report consists of a number of report\_message elements, that contains child elements detailing various aspects for the specific check.

1. Rule, identifies the individual rule (if applicable).
2. Severity, details the severity of a failed check. The values are Error, Warning, Information, Not Applicable.
3. Category, details the type of check.
4. Label, provides a description of the category.
5. Details, provide the details relating to the check (if applicable).
6. Test, this detail is included for advanced user and implementors and identifies the check.
7. Location, this detail is included for advanced user and implementors and identifies the xPath location of the check.

# Validation Report Processing

When a validation report indicates that a check has failed a decision on how to address it must be taken, this section provides a simplified general approach.

* Errors should be resolved prior to submitting content to HPFB as they will likely lead to rejection of the content.
* Warnings should be resolved prior to submitting content to HPFB as they will likely lead to delays in processing the content.
* Information is unlikely to add delays in processing the content and thus may be left unresolved.
* Not Applicable notices can be ignored they identify that while a rule check failed it is not applicable based on the doctype/template/status of the content.