Structured Product Labeling (SPL)
Draft Implementation Guide with
Validation Procedures and User Guide

Version 0.04 Revision 09212016

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1 Introduction

The Environmental Protection Agency's (EPA) SmartLabel Project is an electronic system for submission of pesticide labels, related use information, and tolerance data. The SmartLabel system allows pesticide manufacturers to develop and submit pesticide labels and related use information to EPA for review in an electronic format instead of as paper or PDF files.

SmartLabel strives to make the label review process more efficient by creating a standard template for registrant supplied submission of pesticide label content to EPA, in combination with formatted label use information, allowing for quicker reviews and easier comparisons to previous label versions. Additionally, the data submitted through SmartLabel allows the Agency to set up a searchable database of standardized label content and use data for all products, which can be used in support of risk assessments and registration decisions. This standardized formatting of information also facilitates information sharing between the EPA and other agencies.

This document provides an introduction to the SmartLabel Model, as well as guidance on how to extract pesticide information into the structured product label (SPL) model for submission to the EPA. It is intended that the companion document on the *SmartLabel Vocabulary Guide* (VG) is used in concurrence with this guidance. Additionally, information on the technical conformance criteria is included to provide the "blueprint" for the coding utilized in the SPL xml model.

The Agency hosts a Structured Product Label (SPL) Builder on the EPA's Central Data Exchange (CDX). The SmartLabel SPL Builder is the Agency's publicly offered tool to build, validate, and submit structured xml files to the EPA for review and registration. Other tools may be programed to build and validate SmartLabel xml files by external groups using the technical specifications provided in this document. Files created using external builders must still pass validation and be submitted through the Agency's CDX portal. The *EPA CDX SmartLabel Builder User Guide* should be used in conjunction with this document when using the CDX builder to enter, validate, and submit information to the Agency.

In summary, this document provides the information necessary to understand the technical coding for the builder tool as well as instruction on the submission of a label in to the XML format via entry into the Label Content, Use Index, and Tolerance documents.

1.1 Organization

The body of this document is divided into three parts. The first part of this document (*Section 2*) provides an overview of the standard/model used and the general technical conformance criteria that are applicable to header and body of the SPL document independent of the information being exchanged *i.e.,* the blueprint for the xml form. The second part of the document (*Section* 3) describes the standard/model used and related technical conformance criteria for extracting the pesticide tolerance information as

specified by the United States Code of Federal Regulations (CFR). The third part of the document (*Sections 4 and* 5) describes the standard/model used and the technical conformance criteria used to enter information into the Structured Label Content Model, and the Use Index Model.

Each section is broken into subsections, representing data elements/structured content text blocks or groups of data elements/structured content text blocks. Each subsection is organized as follows:

(# for location in model)   Subsection Title
[Description of subsection data element/structured content]

Entry Type: description of entry type (if any), and name of picklist (if any).

<u>Validation Rules:</u>
(# for location in model)   Human readable rule in black
(# for location in model)   technical programing rule in gray

<u>XML Code Snippet:</u>

```
[box containing xml code for subsection, which can be used
to program alternate SmartLabel xml builders]
```

1.2   Validation Procedures

Detailed validation procedures are presented with most sub-sections and are clearly marked with the heading "Validation Procedures." These procedures can be used by human readers as check-lists to verify if their submission is correct. Additionally, the validation procedures are written as specific and operational so that they may be checked by systems processing SPL documents. Therefore, some validation procedures contain information that refers specifically to SPL standards. Validation procedures that are meant to be used as a check-list when entering information are specified in ***<u>black text</u>***, while SPL technical conformance criteria that are needed to program the xml builder are specified in *<u>grey text</u>*. Validation rules typically include information such as: if a section is required, the number of times a section can be use (0 through # = not required, 1 = required but not duplicable, 1 through # = may be duplicated # number of times), what type of data can be entered (text, number, picklist), picklist that may be used, terms that may be selected, and other relevant information for data entry and programing. Each validation procedure has a unique paragraph number. These paragraph numbers are generally stable over time, but they may change between versions of the document when – rarely – a validation procedure is inserted between existing ones; normally, however, new validation procedures are appended to the end of their respective sub-sections.

2 Overview of SPL Technical Conformance Criteria

Structured Product Labeling (SPL) is a Health Level Seven (HL7) standard based on Clinical Document Architecture and HL7 Reference Information Model (RIM) accredited by the American National Standards Institute (ANSI) for the exchange of product information. Structured Product Labeling documents include a header and body. The header includes information about the document such as the type of document, author and versioning. The body of the document includes product information and labeling content in both structured text and data element formats. The United States Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) uses SPL documents to exchange SmartLabel information regarding pesticide products.

This document provides guidance on how to extract pesticide information into structured models for submission to the EPA, and technical conformance criteria for SPL documents used by EPA's OPP to create the xml builder. Guidance information and validation rules intended for use by those entering data into the model is specified in **_black text_**, while technical conformance criteria intended only for use by those programing an xml builder is specified in _grey text_.

SPL history and background information can be found on the HL7 website: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=401

A reference implementation guide, can be found on the HL7 website: http://www.hl7.org/documentcenter/private/standards/SPL/V3IG_SPL_R5_INFORM_2011MAY.pdf

[Note: These xml technical conformance criteria are still in draft. We suggest not attempting to use them to program your own builder until a later draft of this document is released.]

2.1 SPL Header

2.1.1 General

The following validation rules apply generally to all SPL files submitted to the Agency.

Validation Procedures:

2.1.1.1 XML is well formed and valid against the schema

2.1.1.2 There are no data elements and attributes in addition to those described in this document. Certain exceptions apply to this rule, notably any default attribute that validating schemas would create are by default part

of the document. These need not be stated, but cannot reasonably be forbidden.

2.1.1.3   There are no spaces in codes

2.1.1.4   Codes do not have a codeSystemName attribute

2.1.1.5   Display names are case insensitive

2.1.1.6   There are no spaces in id extensions

2.1.1.7   Letters in Globally Unique Identifiers (GUID) are lower case

2.1.1.8   There are no empty or incomplete elements except, in certain circumstances, code, title, text, and time (an id has a root, a code has a code system).

2.1.1.9   Characteristics have a class code of "OBS" or no class code at all.

2.1.1.10 There is no confidentiality code on anything but inactive ingredients, registrant, and assigned establishments outside establishment registrations.

2.1.1.11 If there is a confidentiality code, then the code is "B" and the codeSystem is "2.16.840.1.113883.5.25"

2.1.2 XML references

This information includes the location of the current stylesheet for the EPA view of the SPL and the location of the current schema. The start of the SPL file is the same for every SPL document and is as follows:

Validation Procedures:

2.1.2.1   XML reference is for version 1.0 and encoding "UTF-8".

2.1.2.2   There is an xml-stylesheet reference to https://cdxnodengn.epa.gov/cdx-smartlabel/public/stylesheet/spl.xsl

2.1.2.3   The schemaLocation of the urn:hl7-org:v3 namespace is provided as "https://cdxnodengn.epa.gov/cdx-smartlabel/public/schema/SPL.xsd "

2.1.2.4   There are no processing instructions other than the xml and xml-stylesheet declarations.

2.1.2.5   There are no comments.

2.1.2.6   SPL file name is the document id followed by ".zip"

2.1.2.7   A submission contains only the SPL file whose name ends in '.zip' and, if appropriate, associated labeling files whose name ends in '.pdf' files or image files whose name ends in '.jpg'.

2.1.2.8   All files associated with the SPL document are actually referenced from that SPL document.

Xml Code Snippet:

```
<?xml version="1.0" encoding="UTF-8"?>
<document xmlns="urn:hl7-org:v3"
      xmlns:xsi=http://www.w3.org/2001/XMLSchema-instance
      xsi:schemaLocation="urn:hl7-org:v3 SPL.xsd">
```

2.1.3 Document Information

This provides basic information for the identity of the particular document, its type, title, date and versioning as a member of a document set.

- The <id root> (also known as **Document ID**) is a Globally Unique Identifier (GUID) and is unique for each version of the document. Letters used in a GUID are lower case. The Document ID is unique and randomly generated.
- The <code> is the **Document Type** code which provides information on the document type.
- The <title> data element is used for the title for the document, if necessary. Images are not included in the title. Multiple lines may be used in the title with each line separated by the line break <br/> tag. (note: all titles can also be as follows: <title mediaType="text/x-hl7-title+xml">).
- The <effectiveTime> (also known as **Effective Date**) provides a date reference to the SPL version including the year, month and day as yyyymmdd. This date is automatically populated when the document is created or updated.
- The <setId> (also known as **Set ID**) is a GUID and is a unique identifier for the document that remains constant through all versions/revisions of the document.
- The <versionNumber> (also known as **Version**) is an integer greater than zero that provides a sequence to the versions of the document. This date is automatically populated when the document is created and should be updated when a new version of the document is submitted.

Validation Procedures:

2.1.3.1   There is a document id
2.1.3.2   id root is a Globally Unique Identifier (GUID).
2.1.3.3   id does not have an extension.
2.1.3.4   id does not match any other id in the document.
2.1.3.5   id (document id) is unique across all documents, sections and any other ids
2.1.3.6   There is a code
2.1.3.7   Code system is 2.16.840.1.113883.6.275.1
2.1.3.8   Code comes from the *Document Type* list
2.1.3.9   Display name matches the code
2.1.3.10 There are no figures in the title.
2.1.3.11 There is an effective time with at least the precision of day in the format YYYYMMDD
2.1.3.12 There is a set id
2.1.3.13 set id is a GUID
2.1.3.14 There is a version number
2.1.3.15 Value of version number is a whole number > 0
2.1.3.16 Value of version number is greater than the value of any previously submitted version for the same set id

Xml Code Snippet:

```xml
<document>
  <id root="50606941-3e5d-465c-b4e0-0f5a19eb41d4"/>
  <code code="Document Type code"
        codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Document Type name"/>
  <title>Title</title>
  <effectiveTime value="20070424"/>
  <setId root="a30accef-f437-4136-808c-9ed4ada5fcf8"/>
  <versionNumber value="1"/>
```

2.1.4 Author Information

This provides basic information about the business responsible for the product, including the company name and number.

Xml Code Snippet:

```xml
<document>
  <author>
    <assignedEntity>
      <representedOrganization>
        <id extension="EPA Company Number"
root="2.16.840.1.113883.6.275.2"/>
        <name>EPA Company Name</name>
      </representedOrganization>
    </assignedEntity>
  </author>
</document>
```

2.1.5 Identified Organizations

The EPA is identified using Dun and Bradstreet identifiers (DUNS numbers). These are identifiers with the root 1.3.6.1.4.1.519.1 and an extension.

Xml Code Snippet:

```xml
<representedOrganization>
  <id extension="057944910" root="1.3.6.1.4.1.519.1"/>
  <name>US Environmental Protection Agency</name>
```

Organizations are identified using EPA registered company numbers. These are identifiers with the root 2.16.840.1.113883.6.275.1 and an extension.

Validation Procedures:

2.1.5.1   There is one id with a root and an extension.
2.1.5.2   There is one name.
2.1.5.3   There are no elements other than id and name.

Criteria

Xml Code Snippet:

```
<representedOrganization>
  <id extension="EPA Company Number" root="2.16.840.1.113883.6.275.1"/>
  <name>EPA Company Name</name>
```

2.2 SPL Body

The body of the SPL documents can include structured text (such as product labeling), structured values (such as percent active ingredient), and/or specific data elements from picklists (such as active ingredients).

Xml Code Snippet:

```
<document> <!-- SPL header material -->
  <component>
    <structuredBody> <!-- SPL body material -->
      <component>
        <section>
```

2.2.1 Sections and subsections

The following is a representative coding for a section.

Xml Code Snippet:

```
<component>
  <section>
    <id root="62abedf9-6bde-4787-beb0-abd214307427"/>
    <code code="3144213"
          codeSystem="2.16.840.1.113883.6.275.1"
          displayName="Directions for Use"/>
    <title>Directions for Use</title>
    <text>labeling text</text>
    <effectiveTime value="YYYYMMDD"/>

  <!-- other elements -->
<component/>
```

Sections and subsections have id, title, and code. The Section Names list provides the codes used for sections and subsections.

The <text>, <title> (if necessary), and the order of the sections and subsections in the SPL are used to render the labeling contents.

In the SPL schema, the <structuredBody> element contains multiple <component> elements, and each <component> contains a <section>.

Sections are used to aggregate paragraphs into logical groupings. The order in which sections appear in an SPL document is the order the sections will appear when displayed (rendered) using the standard stylesheet.

Xml Code Snippet:

```
<section>
  <!-- this section's id, codes -->
  <text>
    <!-- actual text content in "narrative block" markup -->
  </text>
```

Each section has a unique identifier (<id>), an <effectiveTime>, a Section Names code (i.e., the <code> element) and a <title>.

The human readable content of labeling is contained within the <text> element in the <section>. The <section> can be nested to form sub-sections. The schema for subsections in SPL requires that the nested <section> tag first be nested inside a <component> tag. Use nested sections to relate paragraphs. The section tag applies to all of the nested sections.

Xml Code Snippet:

```
<section>
  <!-- this section's id, codes -->
  <text>
    <!-- actual text content in "narrative block" markup -->
  </text>
  <component>
    <section>
      <!-- subsection content -->
    </section>
  </component>
  <component>
    <section>
      <!-- subsection content -->
    </section>
  </component>
</section>
```

Using the following principles for markup of text information improves access to information in labeling:

- Capture the section heading using the <title> element rather than placing the text of the title within the <text> element. This allows computer systems to use and display this information properly.
- Capture the section heading even when the printed label does not include a heading.
- Link different parts of the labeling using the ID attribute to the <section> element. For example, <section ID="Rest_Use_Pest_Section"> serves as the target of a <linkHtml> element. Linking to the ID attribute of a section allows the link to 'reference' the section entirely, e.g., for retrieval of a whole section in a non-browser interface.

Validation Procedures:

2.2.1.1   Each section has zero to many subsections

11

2.2.1.2 Each section and subsection has an id root and no extension
2.2.1.3 id root is a GUID
2.2.1.4 id does not match any other id in the document
2.2.1.5 id does not match any other id across all sections, documents, or any id other than the id of the same section previously submitted
2.2.1.6 Each section and subsection has a code
2.2.1.7 Code system is 2.16.840.1.113883.6.275.1
2.2.1.8 Display name matches the code
2.2.1.9 The section title matches the section code display name except where noted in specific sections of this document.
2.2.1.10 Each section optionally has an effective time with at least the precision of day in the format YYYYMMDD.
2.2.1.11 There are no figures in the title for a section or subsection.

2.2.2 Text

The human readable text content of SPL documents is contained within the <text> element. The actual content is contained within a <paragraph>, <table>, and/or <list>. If a section consists only of nested sections, the <text> tag is not included. Elements that can be used within the <text> element to capture the human readable content of SPL include paragraphs (<paragraph>), lists (<list>), tables (<table>) and images (<renderMultimedia>). Elements permitted as children of the <text> element, used as children of the <paragraph> element or within <table> and <list> include superscripts (<sup>), subscripts (<sub>), links (<linkHtml>), line breaks (<br>), footnotes (<footnote>), footnote references (<footnoteRef>). Images may be included in the content of labeling using the <renderMultiMedia> tag. This tag may be used as a direct child of <text> for 'block' images or as a child of <paragraph> for inline images.

Xml Code Snippet:

```
<section>
  <text>
    <paragraph>Lorem ipsum dolor sit amet, consectetur adipisicing elit,
sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut
enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut
aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit
in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur
sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt
mollit anim id est laborum.</paragraph>
    <paragraph>At vero eos et accusamus et iusto odio dignissimos ducimus
qui blanditiis praesentium voluptatum deleniti atque corrupti quos
dolores et quas molestias excepturi sint occaecati cupiditate non
provident, similique sunt in culpa qui officia deserunt mollitia animi,
id est laborum et dolorum fuga.</paragraph>
  </text>
</section>
```

2.2.2.1 Font effects

There are certain aspects of the rendering of SPL that must be specified in the SPL source to insure that the content of labeling is formatted correctly when rendered. For example:

Xml Code Snippet:

```
<text>
  <paragraph>The next snippet <content styleCode="bold italics">will
appear as bold italics</content> in the rendering.</paragraph>
```

Will be rendered as:

The next snippet ***will appear as bold italics*** in the rendering.
The <content styleCode="'> can also be nested, for example:

Xml Code Snippet:

```
<text>
  <paragraph>
    <content styleCode="bold italics"> will appear as bold
italics</content>
```

Can also be represented as:

Xml Code Snippet:

```
<text>
  <paragraph>
    <content styleCode="bold"><content styleCode="italics"> will appear
as bold italics.</content></content>
```

The values for <styleCode> for font effect are bold, italics and underline. To assist people who are visually impaired, the <styleCode="emphasis"> is used to prompt computer screen reader programs to emphasize text such as text in a box warning. The bold, italics and underline font effects may be used together with each other and the emphasis styleCode. For example, <content styleCode="bold"><content styleCode="emphasis"> </content></content> will appear as bold and will be emphasized by the screen reader programs.

A special styleCode is used for recent major changes (see below).

2.2.2.2   Symbols and special characters

Special characters can be included in the text. Superscripts and subscripts are accomplished using the <sup> and <sub> tags. Because the SPL encoding is UTF-8, any Unicode character can be included as is. Unicode references may also be inserted as either &#dddd; where dddd is the Unicode value in decimal notation or &#xdddd; where dddd is the Unicode value in hexadecimal notation. The font used in the standard stylesheet is a Unicode font assuring that most Unicode characters will be rendered correctly if viewed by a browser supporting this font. The only prohibited characters in XML that cannot be directly used are less-than "<" (because SPL XML tags begin with it) and ampersand "&" (because XML entity references begin with it). Use of these two symbols must be replaced by the XML entity references <. and & respectively. For example, "<paragraph> The mean for group 1 was < 13. </paragraph>" will render

as "The mean for group 1 was <13." and "D&C Yellow #10" will render as "D&C Yellow #10".

2.2.2.3 Footnotes

The SPL schema includes a specific footnote element <footnote>. Footnotes are rendered automatically by the standard SPL stylesheet. <footnoteRef> is used to refer to another (usually earlier) footnote. For example, "<footnote ID="testNote">This is the footnote content</footnote>" will generate the following footnote at the appropriate end of a section. "[6]This is footnote content"

The <footnoteRef> element with the appropriate IDREF attribute, e.g., <footnoteRef IDREF="testNote"/> will display the footnote reference in the text corresponding to the footnote with the same ID, e.g., in this example footnote 6.

Footnotes are rendered by the default stylesheet using Arabic numbers (e.g., 1, 2 3,). Within tables, footnotes are rendered using footnote marks in the series: * † ‡ § ¶ # ♠ ♥ ♦ ♣, effectively separating numbered footnotes within general text and footnotes within tables. Footnotes within tables are rendered at the bottom of the table.

2.2.2.4 Lists

All lists are marked up using the <list> tag, and each item in a list is marked with an <item> tag. The 'listType' attribute identifies the list as ordered (numbered) or unordered (bulleted). The default numbering and bulleting are controlled by the stylesheet.

Lists featuring a standard set of specialized markers (standard specialized lists) can be created using the styleCode attribute with the <list> element. Options available for ordered lists are:

- Arabic (List is ordered using Arabic numerals: 1, 2, 3)
- LittleRoman (List is ordered using little Roman numerals: i, ii, iii)
- BigRoman (List is ordered using big Roman numerals: I, II, III)
- LittleAlpha (List is order using little alpha characters: a, b, c)
- BigAlpha (List is ordered using big alpha characters: A, B, C)'

For example: <list listType="ordered" styleCode="LittleRoman">
For unordered lists the following options exist:

- Disc (List bullets are simple solid discs: ●)
- Circle (List bullets are hollow discs: ○)
- Square (List bullets are solid squares: ■)

For example: <list listType="unordered" styleCode="Disc">

In addition to the standard specialized lists, user-defined characters are also permitted as markers by nesting <caption> within the <item> tag. Note that any character, XML

entity, or Unicode symbol, may be used in the <caption>, and that the <caption> for each <item> are not restricted to the same character.

For example: <item><caption>*</caption> the asterisk is used as item marker here.<item>

Xml Code Snippet:

```
<text>
  <paragraph>Lorem ipsum dolor sit amet, consectetur adipisicing elit,
sed do eiusmod tempor incididunt ut labore et ...</paragraph>
  <list listType="ordered" styleCode="BigRoman">
    <item>Lorem ipsum dolor sit amet,</item>
    <item>consectetur adipisicing slit</item>
  </list>
  <paragraph>At vero eos et accusamus et iusto ...</paragraph>
</text>
```

2.2.2.5   Tables

Tables can be created with the full structure (header (e.g., for column names), body (e.g. for the rows of the table) and footer e.g. for table footnotes)). The element <tbody> is required for an SPL table while the elements <thead> and <tfoot> are optional in the SPL schema. The structure will display a standard typographical table with rules between the caption (table title) and head, the head and body, and the body and <tfoot>. If a <tfoot> element is included and footnotes are present in a table, then footnotes are rendered after the existing content of the <tfoot> element.

It is recommended to always start with a standard table (i.e., <thead> and <tbody> elements) and test to see whether the rendering is unambiguous and interpretable. It is important that the table communicate labeling content **not that it duplicates the presentation in word processed or typeset versions** of the package insert. In the unusual situation where additional formatting is needed, the rule styleCode specified or certain attributes may be used to modify the table.

The rule codes are as follows (note that the control names are case sensitive).
- Rule on left side of cell is Lrule
- Rule on right side of cell is Rrule
- Rule on top of cell is Toprule
- Rule on bottom of cell is Botrule

Note: More than one rule control may be used in a cell, e.g., <td styleCode code="Botrule Lrule">Cell content </td>.

Rule control codes should be used only when necessary for the interpretability of the table. Use of these codes may result in overriding the default rules for tables. Rather than setting the rule for each cell, table rules may also be controlled according to entire rows

or columns by use of the styleCode attributes with <col>, <colgroup>, <thead>, <tfoot>, <tbody> and <tr> elements.

To make row groups appear with horizontal rules, use the styleCode attribute "Botrule" with the appropriate <tr> element. The Botrule value is rarely needed on the <td> element.

The preferred method for using vertical rules is to define colgroup with styleCode="Lrule" or "Rrule" (or both). Only if this does not yield the desired vertical rule should the Lrule or Rrule code value with styleCode attributes on the <td> or <th> element itself be used. Note: In general, vertical rules should not be used. Good typography for tables means using few vertical rules.

To merge cells vertically and horizontally, the rowspan and colspan attributes should be used on the <td>element.

To determine the width of a table, the width attribute may be used on the <table> element and to determine the width of a table column, the width attribute may be used on the <col> and <colgroup> elements.

For horizontal alignment, the preferred method for aligning cell content within the margins is to use <col align=".. "/> in the <colgroup> element, though this can be used in the <colgroup> element as well. Valid values for align are "left", "center", "right", "justify" (for full justification of contents within the cells), and "char" (for character alignment within the cells). Using the <col align=".. "/> markup ensures that the contents for all cells in the column share the same alignment.

For vertical alignment, the align attribute can be used within cells. For cases in which the cell alignment must be different from other cells in the column, align is also available as an attribute on the other table elements, including <td>.

Markup for table footnote is rendered in the <tfoot> tag. This element does not need to be included in SPL; the standard stylesheet will include a <tfoot> tag if a <footnote> element is present within either the <thead> or <tbody> sections. A <tfoot> section should be included in SPL only if there is additional information other than footnotes that needs to be rendered in this section.

For table text spacing, in some instances, the use of a "tab" or text indentation is desirable in a given table cell. In an SPL document, this effect is achieved by using the nonbreaking space ( ) as if it were a "tab" space. As the following snippet of XML shows, two nonbreaking spaces were used to offset the word "Male" from the margin: <td> Male</td>. The nonbreaking space can also be used to keep text in a table from breaking inappropriately due to browser resizing.

2.2.2.6 Hypertext links

SPL offers hypertext linking capabilities generally similar to those found in the HTML specification.

Links are specified by the <linkHtml> construct, where the value for the href attribute of <linkHtml> (the target of the link) is the ID attribute value of a <section>, <paragraph>, <table>, <list>, <content>,<renderMultimedia> element. The stylesheet does not support the styleCode attribute of the <linkHtml> element; if a styleCode is needed for a link, this should be coded via the <content> element within the link as with other text.

2.2.2.7 Recent major changes in labeling text

SPL offers a notation to identify recent major changes in the labeling text including table elements <table> and table data <td>. The recent major text is tagged using the <content styleCode="xmChange">. For example,

> **Validation Procedures:**
> 2.2.2.1   Text is enclosed under <paragraph>, <list>, or <table> elements.

> **Xml Code Snippet:**

```
<text>This is an example of text that is not changed.<content
styleCode="xmChange">This is an example of text that is a recent major
change</content>This is an example of changed text that is not considered
a recent major change</text>
```

2.2.3 Images

The SPL schema uses <observationMedia> elements to identify graphic files to be rendered at the locations where they are referenced by <renderMultiMedia> elements in the <section>. In other words, an image in an SPL will be rendered wherever it is referenced by the renderMultimedia markup, no matter where the observationMedia markup appears. The referencedObject attribute of the renderMultiMedia element identifies the corresponding observationMedia instance by means of its ID identifier such as <renderMultiMedia referencedObject="MM1"/>

The <observationMedia> element does not contain the graphics file, but instead points at the file. The <reference> value is the file name. The file name should not include spaces. The observationMedia identifies the graphic media type (i.e., JPEG). In addition, the observationMedia element includes the text description of the image used by screen reader software for visually impaired users. This is included in the <text> child of <observationMedia>. Note also that observationMedia is always contained within a <component> element as illustrated.

For image placement, if an image is a block image (i.e., should appear in its own space), insert the renderMultimedia tag between <paragraph> elements. If an image is inline (i.e., should appear alongside text), insert the renderMultimedia tag in the text of a

Criteria

<paragraph> as appropriate. Inline images are expected to be uncommon and basically represent symbols that cannot be represented by Unicode characters. In addition, <caption> are not applicable for inline images since these are not offset from the surrounding text.

The SPL stylesheet does not perform any resizing graphics or changing the resolution of graphics files. Thus, all images are rendered in the browser as-is, with all characteristics of the actual graphic file itself. To ensure that a graphic will appear as desired, it is very important that the graphic file is edited to a dimension appropriate for its presentation within the browser. If this is not done, the appearance of the graphic may not be consistent with the narrative content reducing the readability of the file. JPEG image file type using appropriate pixels per inch for images for viewing in a browser using the standard stylesheet.

<u>Validation Procedures:</u>

2.2.3.1 There is text
2.2.3.2 Value xsi:type is "ED".
2.2.3.3 Media type is image/jpeg
2.2.3.4 Reference value is the file name for a valid image
2.2.3.5 Size of image file is less than 1 MB
2.2.3.6 File is a JPEG image and the name has the extension ".jpg"
2.2.3.7 Image components are referenced at least once in the text of any section.
2.2.3.8 Image reference in text has an image "observationMedia" element with a matching ID in the same document.

<u>Xml Code Snippet:</u>

```
<section>
  <text>
    <paragraph>...</paragraph>
    <renderMultiMedia referencedObject="MM1"/>
    <paragraph>...</paragraph>
  </text>
  <component>
    <observationMedia ID="MM1">
      <text>descriptive text</text>
      <value xsi:type="ED" mediaType="image/jpeg">
        <reference value="pesticide-01.jpg"/>
      </value>
    </observationMedia>
  </component>
</section>
```

3   40 CFR 180 TOLERANCE

[Note: *This section is still in draft, and will only be utilized by EPA. A completed section will be inserted in a later draft of this document.]*

4 Pesticide Labeling

The goal of the Label Content document is to capture and display the master label content is a structured and queryable format.

This document captures data in text boxes and as terms from a picklists, and/or value unit combinations. If a picklist is used, the name of the picklist will be listed in the "Entry type" field of each subsection. The items in each picklist and their definitions are compiled on the SmartLabel website:

https://www.epa.gov/pesticide-registration/pesticide-smartlabel-pilot-documents

This document and the definitions it contains can be used as a reference when filling out the Label Content to aid the user in selecting the correct term. If a term to fit your needs cannot be found, please contact *SmartLabel@epa.gov*, for assistance determining the correct term. If an appropriate term cannot be found, a new term can be established and added to the vocabulary. Because new terms will likely be added on a semi-regular basis, please periodically refer to the SmartLabel website for the most current listing of vocabularies and definitions.

4.1 SPL Header

4.1.1 Document type

This is the general subject matter of the Master Label.

Entry type: "Document type" picklist selection.

Validation Procedures

4.1.1.1   Document type is "End-Use Pesticide Label" (3565715).
4.1.1.2   If a document with the same set id has been previously submitted, then it is of the same type.

Xml Code Snippet:

```
<document>
  <code code="3565715"
        codeSystem="2.16.840.1.113883.6.275.1"
        displayName="End-Use Pesticide Label"/>
```

4.1.2 Author Information

This is the company name for the Registrant.

- The ***Company Name***, identifies the name of the organization registering the product using the company name registered with the agency that is associated with the company number entered below.

  Entry type: text

- The **Company Number** identifies the organization registering the product using EPA registered company numbers. These are identifiers with the root 2.16.840.1.113883.6.275.1 and an extension.

  Entry type: value

Validation Procedures

4.1.2.1   There is an author.
4.1.2.2   There are no elements other than id and name.
4.1.2.3   There is one name.
4.1.2.4   The name matches the name in the EPA Company Number List.

Xml Code Snippet:

```
<document>
  <author>
    <assignedEntity>
      <representedOrganization>
        <id root="2.16.840.1.113883.6.275.2"
            extension="EPA Company Number"/>
        <name>EPA Company Name</name>
```

4.2   SPL Body

4.2.1   Sections in General

The Master Label content is included in the Content of Labeling. The content of labeling is divided into sections and subsections. A section or subsection may be associated with data elements.

Validation Procedures:

4.2.1.1   Section codes must come from the "Section Names" list.
4.2.1.2   Section codeSystem is as 2.16.840.1.113883.6.275.1.
4.2.1.3   Section code display name matches the code.
4.2.1.4   Section title is the same as the section code display name except in sections noted in this document.

Xml Code Snippet:

```
<document>
  ...
  <structuredBody>
    <component>
      <section ID="Section Link">
        <id root="Section UUID"/>
        <code code=" codeSystem="2.16.840.1.113883.6.275.1"
              displayName="…">
        <title>Title</title>
        <text>
          ... Section Text (Narrative Block Markup) ...
        </text>
        <effectiveTime value=""/>
        <subject>
```

```
        ... Data Elements ...
      </subject>
      <component>
        <section ID="Section Link">
          ...
```

4.2.2 Restricted Use Pesticide Section

If this product is classified as a Restricted Use Pesticide (RUP), information regarding that classification found in the label RUP box is provided in this text element. This content section describes why the product is considered an RUP and provides a summary statement of the terms of the restriction.

- **If this section applies** to the product, enter the appropriate text in this box.
- **If this section does not apply** to the product, leave the text box blank.
- Reference: 40 CFR Part 156, including the requirements set out in 40 CFR 156.10(j) (2) described further in PR Notice 93-1, and LRM: Chapter 6.
- For example: "Due to Acute Toxicity and Toxicity to Birds and Mammals. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."

Entry type: Text

Validation Procedures:

4.2.2.1   There is one Restricted Use Pesticide section.
4.2.2.2   If text is in the box, then the text "Restricted Use Pesticide" must appear in the "Directions for Use" section.
4.2.2.3   If the product is not considered an RUP, then leave text element blank.
4.2.2.4   The section title is the same as the section code displayName.
4.2.2.5   There are no subsections.

Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144193" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Restricted Use Pesticide"/>
  <title>Restricted Use Pesticide</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
```

4.2.3 Ingredient Statement Section

This content section describes the ingredients contained in the product, including: a listing of active/other ingredients, and their respective nominal concentrations (expressed as a percentage) that when summed equal 100%; any information regarding concentrations of equivalence of the active ingredients (e.g. elemental metallics, acid equivalents, or other moieties); the concentrations of other ingredients that are required to be identified (e.g. petroleum distilates <10% of the formulation); and a conversion factor

expressed as pounds active ingredient (or other standard unit) per gallon product, if the product is packaged in liquid form.

Entry type: Text.

- **Active Ingredient** refers to the active ingredient(s) of the product.
- **Percent Active Ingredient** is the strength of the active ingredient expressed as a percentage. For products which express the strength of the active ingredient as a range, input the high number of the range. For products which express the strength of active ingredient as a qualified value (e.g. ≤) enter the value identified on the label.
- Reference: 40 CFR 156.10(g) and LRM: Chapter 5

Entry type: *"SRS Systematic Name"* selection and value.

Validation Procedures
4.2.3.1   There is an Ingredient Statement section.
4.2.3.2   The section title is the same as the section code displayName.
4.2.3.3   There are one or more active ingredients.
4.2.3.4   There must be text in this section.
4.2.3.5   There are Identified Inert Statement and Deterioration/Expiration Statement subsections.
4.2.3.6   There are no elements other than ingredient.
4.2.3.7   The ingredientSubstance name is required and shall not be blank.

Xml code snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144198" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Ingredient Statement"/>
  <title>Ingredient Statement</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
  <subject>
    <manufacturedProduct>
      <manufacturedProduct>
        <ingredient classCode="ACTIB">
          <quantity>
            <numerator nullFlavor="OTH">
              <translation code="3627136"
                codeSystem="2.16.840.1.113883.6.275.1"
                displayName="%" value="{Percent Value}"/>
            </numerator>
            <denominator value="1"/>
          </quantity>
          <ingredientSubstance>
            <code code="SRS Internal Tracking Number"
              codeSystem="2.16.840.1.113883.6.275"/>
            <name>SRS Systematic Name</name>
          </ingredientSubstance>
```

```
        </ingredient>
        <!-- Additional Ingredients -->
        <ingredient classCode="ACTIB">
          <quantity>

            <numerator nullFlavor="OTH">
              <translation code="3627136"
                codeSystem="2.16.840.1.113883.6.275.1"
                displayName="%" value="{Percent Value}"/>
            </numerator>
            <denominator value="1"/>
          </quantity>
          <ingredientSubstance>
            <code code="SRS Internal Tracking Number"
codeSystem="2.16.840.1.113883.6.275"/>
            <name>SRS Systematic Name</name>
          </ingredientSubstance>
        </ingredient>
```

- **Identified Inert Statement (3565732)**
  This label section includes statements which identify toxic ingredients, petroleum distillates, sodium nitrite, or other compounds which are required to be disclosed.
    - If this section applies to the product, enter the appropriate text in this box.
    - If this section does not apply to the product, leave the text box blank.
    - Reference: LRM Chapter 5

  Entry type: Text

  Validation Procedures:
  4.2.3.8   There is an Identified Inert Statement subsection.
  4.2.3.9   The section title is the same as the section code displayName.

  Xml Code Snippet:
  ```
  <section ID="Section Link">
    <id root="Section UUID"/>
    <code code="3565732" codeSystem="2.16.840.1.113883.6.275.1"
          displayName="Identified Inert Statement"/>
    <title>Identified Inert Statement</title>
    <text/>
    <effectiveTime value="YYYYMMDD"/>
  ```

- **Deterioration/Expiration Statement (3144196)**
  This label section includes statements regarding the deterioration of a product during storage. In cases where it is determined that a pesticide formulation changes chemical composition significantly over time, the product must bear a statement in this subsection of the label.

    - If this section applies to the product, enter the appropriate text in this box.
    - If this section does not apply to the product, leave the text box blank.
    - Reference: 40 CFR 156.10(g)(6)(i); LRM Chapter 5
    - For example: "Not for sale or use after (date)". "Degrades with age…"

Entry type: Text

Validation Procedures:
4.2.3.10 There is a Deterioration/Expiration Statement Subsection.
4.2.3.11 The section title is the same as the section code displayName.

Xml Code Snippet:
```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144196" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Deterioration/Expiration Statement"/>
  <title>Deterioration/Expiration Statement</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
```

4.2.4 Child Hazard Warning/Signal Word Section

This content section includes statements regarding the Child Hazard Warning and the Signal Word with the associated statements and images. For example, the Child Hazard Warning may include, "Keep out of Reach of Children." The associated language and image can include, "Poison," skull and cross-bones, Spanish translation of the signal word, and/or the statement "Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)"

Entry type: Text.

- **Signal Word -** This label attribute is the selection of a signal word from a defined set of terminology.
    - Reference: LRM Chapter 7 and 10; 40 CFR 156.206(e)

Entry type: "*Signal Word***"** picklist selection.

Validation Procedures:
4.2.4.1 There is a Child Hazard Warning/Signal Word section.
4.2.4.2 The section title is the same as the section code displayName.
4.2.4.3 There is no other data element than asSpecializedKind.
4.2.4.4 There is a Child Hazard Warning/Signal Word code.
4.2.4.5 Code comes from the list *Signal Word*.
4.2.4.6 Display name matches the code.

Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3567150" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Child Hazard Warning/Signal Word"/>
  <title>Child Hazard Warning/Signal Word</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
  <subject>
    <manufacturedProduct>
      <manufacturedProduct>
        <asSpecializedKind>
          <generalizedMaterialKind>
            <code code="Signal Word code"
                  codeSystem="2.16.840.1.113883.6.275.1"
                  displayName="Signal Word name"/>
```

4.2.5 Product Profile

This label section includes language that is unique to the product and that generally occurs on the front page of the product label, including: Primary Brand Name, Alternate Brand Name(s), Product Number, Pesticide Classification, EPA Establishment Number, Company Name and Address, Net Contents or Net Weight, and Batch Code. This section also includes the paragraph or phrase typically found under the product name that describes the type of product, formulation, its uses, pests it controls, and other categories or descriptors (e.g., resistance management category). This content section may also include any other descriptors for the product that are NOT contained in the "Ingredient Statement," "Precautionary Statements," "Directions for Use," "Warranty/Disclaimer Statements," and "Marketing/Advertising Claims" sections.

> **Entry type:** Text.

- **EPA Registration Number** is a unique identifier for each registered pesticide product. It is comprised of the EPA Company Number and the EPA Product Number, separated by a dash. The **Product Number** captures only the EPA Product Number. The EPA Company number is captured in the Author section defined above.

> **Entry type:** value.

- **Primary Brand Name** is the product brand name.

> **Entry type:** Text.

- **Form as Packaged** describes the physical state and attributes of the product as packaged. If the product is a liquid, the type of liquid (ex. Solution, Suspension, Emulsion, or Gel/Grease/Paste) is selected. If the

product is a solid, the type of solid (ex. Granule, Dust/Powder, Crystalline, Solidified Agar, Impregnated Material, or Pellet/Tablet/Rodlet/Briquette) is selected. If the product is packaged as a Gas, then Gas/Vapor is selected.

- o For example:
    - A Water Dispersible Granule product is packed as a "granule" which is associated with the broader term "solid".
    - A Wettable Powder product is packed as a "dust/powder" which is associated with the broader term "solid".
    - A Suspension Concentrate is packaged as a "suspension" which is associated with the broader term "liquid".

Entry type: "*Pesticide Form***" picklist selection.**

- **Pesticide Classification** describes the product according to the type of pest targeted and the function of the pesticide against the pest (e.g., fungicide, herbicide, disinfectant).

Entry type: "*Pesticide Classifications*" picklist selection.

- **Alternate Brand Name(s)** This includes any names other than the Primary Brand Name under which this product may be sold.

Entry type: Text.

Validation Procedures:

4.2.5.1   There is a Product Profile section.
4.2.5.2   The section title is the same as the section code displayName.
4.2.5.3   There is one Product number per document.
4.2.5.4   There is one Primary Brand Name.
4.2.5.5   There can be zero to many Alternate Brand Names.
4.2.5.6   Alternate Brand Names are unique; no duplicates.
4.2.5.7   No Alternate Brand Name is the same as the Primary Brand Name.
4.2.5.8   There is one or more pesticide classification.
4.2.5.9   Code comes from the list *Pesticide Classifications*.
4.2.5.10 Display name matches the code.
4.2.5.11 There is one form as Packaged.
4.2.5.12 Code comes from the list *Pesticide Form*.
4.2.5.13 Display name matches the code.

Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144190" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Product Profile"/>
```

```
<title>Product Profile</title>
<text/>
<effectiveTime value="YYYYMMDD"/>
<subject>
  <manufacturedProduct>
    <manufacturedProduct>
      <code code="Product Number"
            codeSystem="2.16.840.1.113883.6.275.2"/>
      <name>Primary Brand Name</name>
      <formCode code="Physical Form code"
                codeSystem="2.16.840.1.113883.6.275.1"
                displayName="Physical Form name"/>
      <asNamedEntity>
        <name>Alternate Brand Name</name>
      </asNamedEntity>
        <!-- Additional Alternate Brand Names -->
      <asNamedEntity>
        <name>Alternate Brand Name</name>
      </asNamedEntity>
      <asSpecializedKind>
        <generalizedMaterialKind>
          <code code="Pesticide Classification code"
                codeSystem="2.16.840.1.113883.6.275.1"
                displayName="Pesticide Classification name"/>
        </generalizedMaterialKind>
      </asSpecializedKind>
      <!-- Additional Pesticide Classifications -->
      <asSpecializedKind>
        <generalizedMaterialKind>
          <code code="Pesticide Classification code"
                codeSystem="2.16.840.1.113883.6.275.1"
                displayName="Pesticide Classification name"/>
        </generalizedMaterialKind>
      </asSpecializedKind>
    </manufacturedProduct>
    <subjectOf>
```

4.2.6 Precautionary Statements

The content for this label section is contained within the subsections. It includes the statement "Keep Out of Reach of Children." Sometimes a modified statement may be more appropriate (see CFR Part 156.66 (b)). In those instances, the alternative statement may be entered into the free text box for approval by the Agency.

Validation Procedures:

4.2.6.1   There is a Precautionary Statements section.
4.2.6.2   The section title is the same as the section code displayName.

Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144199" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Precautionary Statements"/>
  <title>Precautionary Statements</title>
  <effectiveTime value="YYYYMMDD"/>
```

- **First Aid** (3144200) – includes required and optional first aid statements for the four routes of exposure. Starting with the highest toxicity category, enter each route of exposure (e.g. "If Swallowed") and its required language. This section also includes general information used when calling a poison control center, doctor, or National Pesticides Information Center. Also, includes the Note to Physician with specific medical treatment directions for a medical professional to follow in situations of exposure.
  - If this section applies to the product, enter the appropriate text in this box.
  - If this section does not apply to the product, leave the text box blank.
  - Reference: 40 CFR 156.68; LRM Chapter 7

    Entry type: Text.

    Validation Procedures
    4.2.6.3   There is a First Aid subsection.
    4.2.6.4 The section title is the same as the section code displayName.

    Xml Code Snippet:
    ```
    <section ID="Section Link">
      <id root="Section UUID"/>
      <code code="3144200" codeSystem="2.16.840.1.113883.6.275.1"
            displayName="First Aid"/>
      <title>First Aid</title>
      <text/>
      <effectiveTime value="YYYYMMDD"/>
    ```

- **Hazard to Humans and Domestic Animals** (3144205) – includes "Precautionary Statements", the product's signal word, and statement(s) that describe the particular hazard, route of exposure, and precautions to be taken. These statements are determined by the acute toxicology assessment and must be written verbatim.
  - If this section applies to the product, enter the appropriate text in this box.
  - If this section does not apply to the product, leave the text box blank.
  - Reference: 40 CFR 156.70; LRM Chapter 7

    Entry type: Text.

Validation Procedures

4.2.6.5   There is a Hazards to Humans and Domestic Animals subsection.
4.2.6.6   The section title is the same as the section code displayName.

Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144205" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Hazards to Humans and Domestic Animals"/>
  <title>Hazards to Humans and Domestic Animals</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
```

- **Personal Protective Equipment** (3144206) – lists all of the required personal protective equipment (PPE). This includes requirements for clothing, respiratory protection, and protective eyewear for uses covered under the Worker Protection Standard (WPS) as well as label-required baseline work clothes for end-use occupational use products (non-WPS).
    - If this section applies to the product, enter the appropriate text in this box.
    - If this section does not apply to the product, leave the text box blank.
    - Reference: 40 CFR 170.240; LRM Chapter 10

    Entry type: Text.

    ### Validation Procedures:

    4.2.6.7   There is a Personal Protective Equipment subsection.
    4.2.6.8   The section title is the same as the section code displayName.

    ### Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144206" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Personal Protective Equipment"/>
  <title>Personal Protective Equipment</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
```

- **Engineering Controls Statement** (3144207) – describes any reductions or modifications to handler PPE requirements that may be made in the presence of certain engineering controls (e.g., closed systems, enclosed cabs, lock and load containers). Engineering controls may be required by a regulatory assessment or by the acute toxicity profile.
    - If this section applies to the product, enter the appropriate text in this box.
    - If this section does not apply to the product, leave the text box blank.
    - Reference: 40 CFR 170.240 (d) (4-6). LRM Chapter 10.

- For example: When handlers use closed systems, enclosed cabs, or aircraft, in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

Entry type: Text.

Validation Procedures:

4.2.6.9   There is an Engineering Controls Statement subsection.
4.2.6.10 The section title is the same as the section code displayName.

Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144207" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Engineering Controls Statement"/>
  <title>Engineering Controls Statement</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
```

- **User Safety requirements** (3144208) – includes label language for maintaining PPE and handling contaminated PPE, as well as any specific user safety requirements described in RED documents and other Agency document that this section is required for all occupational use products, both WPS and non-WPS.
  - Reference: 40 CFR 170.240, 40 CFR156.200-212. LRM Chapter 10.
  - For example: "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."
  - If this section applies to the product, enter the appropriate text in this box.
  - If this section does not apply to the product, leave the text box blank.

Entry type: Text.

Validation Procedures:

4.2.6.11 There is a User Safety Requirements subsection.
4.2.6.12 The section title is the same as the section code displayName.

Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144208" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="User Safety Requirements"/>
  <title>User Safety Requirements</title>
```

```
<text/>
<effectiveTime value="YYYYMMDD"/>
```

- **User Safety recommendations** (3144209) –This label section includes user safety information and additional recommendations for users of products that fall within the scope of the WPS. These statements are required for all WPS products but are also required for many non-WPS occupational use products based upon regulatory assessments.
    - If this section applies to the product, enter the appropriate text in this box.
    - If this section does not apply to the product, leave the text box blank.
    - Reference: PR Notice 93-7, Supplement Three. LRM Chapter 10.
    - For example: "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

    Entry type: Text.

    Validation Procedures:
    4.2.6.13 There is a Use Safety Recommendations subsection.
    4.2.6.14 The section title is the same as the section code displayName.

    Xml Code Snippet:
```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144209" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="User Safety Recommendations"/>
  <title>User Safety Recommendations</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
```

- **Environmental Hazards** (3144210) – provides precautionary information on potential hazards to the environment from transport, use, storage, or spill of the product based on environmental fate and toxicity data. These hazards may be to water, soil, air, or to animals or plants. This section may also contain other mandatory environmental label statements (e.g. Aquatic Weed Control Statement, Irrigation Water Statement, Mosquito Control Statement, Endangered Species Bulletins, Point Discharge Statement, and Seed Treatment Statement).
    - Reference: 40 CFR 156.80-85; LRM Chapter 8.
    - If this section applies to the product, enter the appropriate text in this box.
    - If this section does not apply to the product, leave the text box blank.

    Entry type: Text.

4.2.6.15 There is an Environmental Hazards subsection.
4.2.6.16 The section title is the same as the section code displayName.

Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144210" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Environmental Hazards"/>
  <title>Environmental Hazards</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
```

- **Physical and Chemical Hazards** (3144212) – includes language and symbols regarding physical or chemical hazards for the product, as well as the various required precautions identified in the product chemistry review. If this section applies to the product, enter the appropriate text in this box.
  - Reference: 40 CFR 156.78. LRM Chapter 9
  - For example: "Combustible. Do not use or store near heat or open flame."
  - If this section does not apply to the product, leave the text box blank.

Entry type: Text.

Validation Procedures:

4.2.6.17 There is a Physical and Chemical Hazards subsection.
4.2.6.18 The section title is the same as the section code displayName.

Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144212" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Physical and Chemical Hazards"/>
  <title>Physical and Chemical Hazards</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
```

4.2.7 Directions for Use

Include the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." Other statements relating to misuse are acceptable for residential/household-use products (e.g., "Read the Label First"). These additional statements can appear on the label following the required misuse statement noted above. Other products may require additional language (e.g. "Do not apply this product in a way that will contact workers or other persons, either directly or through drift." "Only protected handlers may be in the area during application" or "For any requirements

specific to your state or tribe, consult the state or tribal agency responsible for pesticide regulation.")
Reference: LRM Chapter 11

Entry type: Text.

Validation Procedures:
4.2.7.1   There is a Directions for Use section.
4.2.7.2   The section title is the same as the section code displayName.
4.2.7.3   The following statement must be in this text box: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144213" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Directions for Use"/>
  <title>Directions for Use</title>
  <text>
    <paragraph>It is a violation of Federal law to use this product in a
manner inconsistent with its labeling.</paragraph>
  </text>
  <effectiveTime value="YYYYMMDD"/>
```

- **Agricultural Use Requirements** (3144215) – includes all text associated with the Agricultural Use Requirements box, including early entry PPE and Restricted Entry Interval (REI) information.
  - If this section applies to the product, enter the appropriate text in this box.
  - If this section does not apply to the product, leave the text box blank.
  - **Reference**: WPS-required language can be found in CFR 156.206.

Entry type: Text.

Validation Procedures:
4.2.7.4   There is an Agricultural Use Requirements subsection.
4.2.7.5   The section title is the same as the section code displayName.

Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144215" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Agricultural Use Requirements"/>
  <title>Agricultural Use Requirements</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
```

- **Non Agricultural Use Requirements** (3144216) – includes any applicable use requirements that are not within the scope of WPS. Enter the statement, "The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part170)," as well as any entry restrictions, notification requirements, or other statements and instructions that apply to the non-WPS uses on the label.
  - This section only needs to be entered if the label includes both WPS and non-WPS use sites.
  - If this section applies to the product, enter the appropriate text in this box.
  - If this section does not apply to the product, leave the text box blank.

  Entry type: Text.

  Validation Procedures:
  4.2.7.1   There is a Non Agricultural Use Requirements subsection.
  4.2.7.2   The section title is the same as the section code displayName.

  Xml Code Snippet:
```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144216" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Non Agricultural Use Requirements"/>
  <title>Non Agricultural Use Requirements</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
```

- **Resistance Management** (3144217) – provides details on precautions, directions, and restrictions related to resistance management of the chemistries of the product and frequently references the IRAC/HRAC/FRAC groups or Integrated Pest Management (IPM) practices. If "Biopesticide: Plant Incorporated Protectant" is selected for the Pesticide Category, then this section must be included.
- If this section applies to the product, enter the appropriate text in this box.
- If this section does not apply to the product, leave the text box blank.

  Entry type: Text.

  Validation Procedures:
  4.2.7.1   There is a Resistance Management subsection.
  4.2.7.2   The section title is the same as the section code displayName.

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Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144217" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Resistance Management"/>
  <title>Resistance Management</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
```

- **Spray Drift** (3144230) – includes any mandatory spray drift prevention language as well as any advisory language that is applicable to the product.
  - If this section applies to the product, enter the appropriate text in this box.
  - If this section does not apply to the product, leave the text box blank.

  Entry type: Text.

  Validation Procedures:
  4.2.7.1   There is a Spray Drift subsection.
  4.2.7.2   The section title is the same as the section code displayName.

  Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144230" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Spray Drift Management"/>
  <title>Spray Drift Management</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
```

- **Rotational Crop Intervals** (3144229) – includes statements regarding the timing of planting for subsequent food/feed crops or cover crops following failure/harvest of a treated crop. Also contains relevant information on grazing/harvest restrictions. Plant-back intervals are typically expressed in days or months. It is recommended that this information is displayed in a table for ease of use.
  - If this section applies to the product, enter the appropriate text in this box.
  - If this section does not apply to the product, leave the text box blank.

  Entry type: Text.

  Validation Procedures:
  4.2.7.1   There is a Rotational Crop Intervals subsection.
  4.2.7.2   The section title is the same as the section code displayName.

Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144229" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Rotational Crop Intervals"/>
  <title>Rotational Crop Intervals</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
```

- **Seed Bag Labeling Requirements** (3144214) – contains instructions to the applicator/seed treater regarding labeling requirements for bags containing treated seed.

    - Required Seed bag if it applies must include the language required under the Federal Seed Act:

      (1) A word or statement indicating that the seeds have been treated;
      (2) The commonly accepted coined, chemical (generic), or abbreviated chemical name of any substance used in such treatment;
      (3) If the substance used in such treatment in the amount remaining with the seeds is harmful to humans or other vertebrate animals, an appropriate caution statement provided by the Secretary of Agriculture as adequate for the protection of the public, such as "Do not use for food or feed or oil purposes."

    - Seed bag labeling may also include statements requested by EPA that are intended to provide the end-user of the treated seed with precautionary and hazard information, planting requirements, disposal instructions, and other restrictions (e.g., PPE for the planter, minimum planting depth, seeding rate restrictions, plant-back restrictions, excess seed disposal instructions).

    - If this section applies to the product, enter the appropriate text in this box.

    - If this section does not apply to the product, leave the text box blank.

    Entry type: Text.

    Validation Procedures:
    4.2.7.1   There is a Seed Bag Labeling Requirements subsection.
    4.2.7.2   The section title is the same as the section code displayName.

    Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144214" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Seed Bag Labeling Requirements"/>
  <title>Seed Bag Labeling Requirements</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
```

- **Storage and Disposal Subsection** (3144244) – Contains information on storage, pesticide disposal, and container handling/disposal. This section has further data elements, see details in section 0 below.
    - All products, except for residential/household-use products, must bear the following statement: "Do not contaminate water, food, or feed by storage or disposal."
    - All products must contain storage statements, which may be chemical-specific (as identified by EPA in the LRM) or non-chemical specific.
    - Pesticide disposal instructions include information on how to dispose of leftover pesticide. Pesticide disposal and container handling statements are generally specific to the uses of the product contained and the type of container itself. For residential/household-use products, pesticide disposal and container handling statements may be combined.
    - Container handling instructions include information on whether the container is refillable or non-refillable, a reuse statement, a recycling/reconditioning statement, and information on how to remove residues from emptied pesticide containers and what to do with the pesticide container after it is emptied. Plant-incorporated protectants, pesticidal articles not exempted from FIFRA by §152.25(a), transport vehicles, and products listed in §156.140(a) (5) are not required to have refillable/non-refillable and reuse statements.

    Reference: LRM Chapter 13

    Entry type: Text.

    Validation Procedures:
    4.2.7.1   There is a Storage and Disposal subsection.
    4.2.7.2   The section title is the same as the section code displayName.

    Xml Snippet:
    ```
    <section ID="Section Link">
      <id root="Section UUID"/>
      <code code="3144244" codeSystem="2.16.840.1.113883.6.275.1"
            displayName="Storage and Disposal"/>
      <title>Storage and Disposal</title>
      <text/>
      <effectiveTime value="YYYYMMDD"/>
    ```

4.2.8   Storage and Disposal Data Elements

Container type identifies the types of containers in which this product is packaged.

Entry type: "*FormCode*" picklist selection.

Validation Procedures:

4.2.8.1   Storage and disposal subsection has a product element.
4.2.8.2   The section title is the same as the section code displayName.
4.2.8.3   There are no elements other than code and asContent.
4.2.8.4   There is an asContent element for the package description.
4.2.8.5   Package has a formCode with codeSystem as above.
4.2.8.6   The code comes from the list *FormCode*.
4.2.8.7   Display name matches the code.

Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144244" codeSystem="2.16.840.1.113883.6.275.1"
displayName="Storage and Disposal"/>
  <title>Storage and Disposal</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
  <subject>
    <manufacturedProduct>
      <manufacturedProduct>
        <asContent>
          <containerPackagedProduct>
            <formCode code="Container Type code"
                      codeSystem="2.16.840.1.113883.6.275.1"
                      displayName="Container Type name"/>
          </containerPackagedProduct>
        </asContent>
        <!-- Additional Container Types -->
        <asContent>
          <containerPackagedProduct>
            <formCode code="Container Type code"
                      codeSystem="2.16.840.1.113883.6.275.1"
                      displayName="Container Type name"/>
          </containerPackagedProduct>
        </asContent>
      </manufacturedProduct>
    </manufacturedProduct>
```

- **Product Application Instructions/Information** (3144218) – includes any product application instructions that are consistent across all labeled use sites not described in the sections above. Information in this section includes: directions to the users for opening the package (e.g., shake before using and specific child-resistant packaging instructions); application methods and equipment instructions (e.g., aerial, ground, chemigation); environmental conditions (e.g., soil temperature, soil type, air temperature); product restrictions; product advisory statements; tank mix and compatibility (Includes instructions for diluting and/or mixing the product with other chemicals prior to application.
- Reference Chapter 11, Section 11-22 of the Label Review Manual
- This subsection has further data elements, see Section 0 below.
- If this section applies to the product, enter the appropriate text in this box.
- If this section does not apply to the product, leave the text box blank.

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Entry type: Text.

Validation Procedures:

4.2.8.8   There is a Product Application Instructions subsection.
4.2.8.9   The section title is the same as the section code displayName.

Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144218" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Product Application
Instructions/Information"/>
  <title>Product Application Instructions/Information</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
```

4.2.9   Product Application Instructions/Information Data Elements

This main section includes any product application instructions that are consistent across all labeled use sites not described in the sections above. Information in this section includes: directions to the users for opening the package (e.g., shake before using and specific child-resistant packaging instructions); application methods and equipment instructions (e.g., aerial, ground, chemigation); environmental conditions (e.g., soil temperature, soil type, air temperature); product restrictions; product advisory statements; tank mix and compatibility (including instructions for diluting and/or mixing the product with other chemicals prior to application. Refer to section 11-22 of the Label Review Manual for more information on what to include in this section).

- **Use Site Application Instructions Section Text-**this label section includes application instructions specific to the use site, such as application rate, number of applications, reapplication interval, application timing, target pest, site-specific restrictions, etc.

    Entry type: Text.

- **Use Site -** Identifies the use site. For crop use sites, the list includes all crops and crop groups. For non-crop use sites the list is comprised of higher level categories. See the use site guidance document and "Use Site/Commodity" for guidance. [Placeholder - See [link to list] for non-crop use site terminology.]

    Entry type: "*Use Site/Commodity*" picklist selection.

- **Location -** gives a broad category-based description of where the pesticide treatment is taking place (e.g. Agricultural (indoor), Agricultural (outdoor),

Medical/Hospital/Veterinary Facility (Indoor), etc). The Use Site and Use Site Location work together to fully define where pesticide application occurs.

Entry type: "*Use Site Location*" picklist selection.

- **Action -** identifies the action/effect of the pesticide (e.g., action against disease, action against pest, plant regulator)

Entry type: "*Pesticide Action*" picklist selection.

Validation Procedures
4.2.9.1   There is Use Site Application Instructions subsection.
4.2.9.2   The section title may be the same as the section code displayName.
4.2.9.3   There is a substanceAdministration element.
4.2.9.4   There are one or more Use Site Locations (approachSiteCode element).
4.2.9.5   The Use Site Location comes from the list *Use Site Location.*
4.2.9.6   There is one and only one Use Site (presentSubstance/presentSubstance element).
4.2.9.7   There is a Use Site code.
4.2.9.8   Use Site code system is 2.16.840.1.113883.6.275.1.
4.2.9.9   Use Site code comes from the list *Registered Use Site*.
4.2.9.10 There is a Use Site name.
4.2.9.11 Use Site name matches the code.
4.2.9.12
4.2.9.13 There are one or more Pesticide Action elements.
4.2.9.14 Pesticide Action has an effect code.
4.2.9.15 Pesticide Action code system is 2.16.840.1.113883.6.275.1
4.2.9.16 Pesticide Action code comes from the list *Pesticide Action*.
4.2.9.17 Pesticide Action display name matches the code.

Xml Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144218" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Product Application Instructions/Information"/>
  <title>Product Application Instructions/Information</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
  <component>
    <section ID="Section Link">
      <id root="Section UUID"/>
      <code code="3144234" codeSystem="2.16.840.1.113883.6.275.1"
            displayName="Use Site Application Instructions"/>
      <title>Use Site Application Instructions</title>
      <text/>
      <effectiveTime value="YYYYMMDD"/>
      <subject2>
```

```
        <substanceAdministration>
          <subject>
            <approachSiteCode code="{Use Site Location Code}"
                      codeSystem="2.16.840.1.113883.6.275.1"
                      displayName="{DisplayName}"/>
            <!-- Additional Use Site Locations -->
            <approachSiteCode code="{Use Site Location Code}"
                      codeSystem="2.16.840.1.113883.6.275.1"
                      displayName="{DisplayName}"/>
            <presentSubstance classCode="LOCE">
              <presentSubstance>
                <code code="Use Site/Commodity code"
                      codeSystem="2.16.840.1.113883.6.275.1"/>
                <name>Use Site/Commodity name</name>
              </presentSubstance>
            </presentSubstance>
          </subject>
          <goal typeCode="OBJF">
            ... Pesticide Action Against Pest ...
            ... Pesticide Action Against Disease ...
            ... Pesticide Action - Plant Regulator ...
          </goal>
          <!-- Additional Pesticide Actions -->
          <goal typeCode="OBJF">
            ... Pesticide Action Against Pest ...
            ... Pesticide Action Against Disease ...
            ... Pesticide Action - Plant Regulator ...
          </goal>
        </substanceAdministration>
      </subject2>
    </section>
  </component>
  <!-- Additional Use Site Application Instructions -->
  <component>
    <section ID="Section Link">
      <id root="Section UUID"/>
      <code code="3144234" codeSystem="2.16.840.1.113883.6.275.1"
            displayName="Use Site Application Instructions"/>
      <title>Use Site Application Instructions</title>
      <text/>
      <effectiveTime value="YYYYMMDD"/>
      <subject2>
        <substanceAdministration>
          <subject>
            <presentSubstance classCode="LOCE">
              <approachSiteCode code="{Use Site Location Code}"
                              codeSystem="2.16.840.1.113883.6.275.1"
                              displayName="{DisplayName}"/>

              <!-- Additional Use Site Locations -->
              <approachSiteCode code="{Use Site Location Code}"
                              codeSystem="2.16.840.1.113883.6.275.1"
                              displayName="{DisplayName}"/>
              <presentSubstance>
                <code code="Use Site/Commodity code"
                      codeSystem="2.16.840.1.113883.6.275.1"/>
                <name>Use Site/Commodity name</name>
              </presentSubstance>
            </presentSubstance>
          </subject>
          <goal typeCode="OBJF">
            ... Pesticide Action Against Pest ...
            ... Pesticide Action Against Disease ...
            ... Pesticide Action - Plant Regulator ...
```

```
            </goal>
          </substanceAdministration>
        </subject2>
      </section>
  </component>
```

4.2.10 Pesticide Action Against Pest

Identifies the action/effect of the pesticide (e.g., action against disease, action against pest, plant regulator)

- **Pest** identifies the target pest.

  Entry type: *"Pest"* picklist selection.

- **Pest Stage** identifies the development stages of the target pest.

  Entry type: "*Pest Stage*" picklist selection.

Validation Procedures:

4.2.10.1   If the pesticide action code is an Action Against Pest, then there is a Pesticide Subaction.

4.2.10.2   Pesticide Subaction has a code.

4.2.10.3   Pesticide Subaction code system is 2.16.840.1.113883.6.275.1

4.2.10.4   Pesticide Subaction code comes from the list *Pesticide Sub Action*.

4.2.10.5   Pesticide Subaction display name matches the code.

4.2.10.6   If the pesticide action code is an Action Against Pest, then there must be a Target Pest element.

4.2.10.7   Each occurrence of Target Pest has a code.

4.2.10.8   Target Pest code system is 2.16.840.1.113883.6.275.1

4.2.10.9   Target Pest code comes from the list *Target*.

4.2.10.10 Target Pest display name matches the code.

4.2.10.11 Target Pest must have one or more Pest Stage characteristic(s).

4.2.10.12 Pest Stage list has code is 1004703.

4.2.10.13 Pest Stage characteristic code system is 2.16.840.1.113883.6.275.1

4.2.10.14 Pest Stage characteristic value display name matches the code.

4.2.10.15 The Pest Stage characteristic value code comes from the list *Pest Stage*.

Xml Code Snippet:

```
            <goal typeCode="OBJF">
              <effect>
                <code code="3852165"
                      codeSystem="2.16.840.1.113883.6.275.1"
                      displayName="Action Against Pest">
                  <qualifier xsi:type="CR">
                    <value code="Pesticide Subaction code"
                           codeSystem="2.16.840.1.113883.6.275.1"
                           displayName="Pesticide Subaction name"/>
                  </value>
                  </qualifier>
                </code>
                <subject>
                  <presentSubstance classCode="LOCE">
```

```
                    <presentSubstance>
                     <code code="Target Pest code"
                           codeSystem="2.16.840.1.113883.6.275.1"/>
                     <name>Target Pest name</name>
                    </presentSubstance>
                    <subjectOf>
                     <characteristic>
                       <code code="3567152"
                             codeSystem="2.16.840.1.113883.6.275.1"
                             displayName="Pest Stage"/>
                       <value xsi:type="CD"
                             code="Pest Stage code"
                             displayName="Pest Stage name"/>
                     </characteristic>
                    </subjectOf>
                   </presentSubstance>
                 </subject>
               </effect>
            </goal>
```

4.2.11 Pesticide Action Against Disease

Identifies the action/effect of the pesticide (e.g., action against disease, action against pest, plant regulator)

> **Entry type:** "*Plant Disease Sub Action*" and/or "*Plant Disease*" picklist selections.

- **Plant Disease** identifies the target plant disease.
  Entry type: "*Plant Disease"* picklist selection.

Validation Procedures:
4.2.11.1   If the pesticide action code is an Action Against Disease, then there is a Plant Disease Subaction.
4.2.11.2   Plant Disease Subaction has a code.
4.2.11.3   Plant Disease Subaction code system is 2.16.840.1.113883.6.275.1
4.2.11.4   Plant Disease Subaction code comes from the list *Plant Disease Sub Action.*
4.2.11.5   Plant Disease Subaction display name matches the code.
4.2.11.6   If the pesticide action code is an Action Against Disease, then there is a Plant Disease element.
4.2.11.7   Plant Disease has a code.
4.2.11.8   Plant Disease code system is 2.16.840.1.113883.6.275.1
4.2.11.9   Plant Disease code comes from the list *Plant Disease.*
4.2.11.10 Plant Disease display name matches the code.

Xml code snippet:

```
            <goal typeCode="OBJF">
              <effect>
                <code code="3852166"
                      codeSystem="2.16.840.1.113883.6.275.1"
                      displayName="Action Against Disease">
                 <qualifier xsi:type="CR">
                   <value code="Plant Disease Subaction code"
```

```
                        codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Plant Disease Subaction name"/>
                </value>
              </qualifier>
          </code>
          <subject>
            <presentSubstance classCode="LOCE">
              <presentSubstance>
                <code code="Plant Disease code"
                      codeSystem="2.16.840.1.113883.6.275.1"/>
                <name>Plant Disease name</name>
              </presentSubstance>
            </presentSustance>
          </subject>
        </effect>
      </goal>
```

4.2.12 Pesticide Action - Plant Regulator

Identifies the function of the plant regulator.

Entry type: "*Plant Regulator Function*" picklist selections.

Validation Procedures:
4.2.12.1 If the pesticide action code is a Plant Regulator, then there is a Plant
         Regulator Function element.
4.2.12.2 Plant Regulator Function has a code.
4.2.12.3 Plant Regulator Function code system is 2.16.840.1.113883.6.275.1
4.2.12.4 Plant Regulator Function code comes from the list *Plant Regulator
         Function*.
4.2.12.5 Plant Regulator Function display name matches the code.

Xml Code Snippet:
```
      <goal typeCode="OBJF">
        <effect>
          <code code="3852167"
                codeSystem="2.16.840.1.113883.6.275.1"
                displayName="Plant Regulator">
            <qualifier xsi:type="CR">
              <value code="Plant Regulator Function code"
                     codeSystem="2.16.840.1.113883.6.275.1"
                     displayName="Plant Regulator Function name"/>
            </qualifier>
          </code>
        </effect>
      </goal>
```

4.2.13 Warranty/Disclaimer Statement

Language describing the warranty and disclaimer statement, and/or terms of use for the product.

- If this section applies to the product, enter the appropriate text in this box.
- If this section does not apply to the product, leave the text box blank.

Reference: LRM Chapter 12

Entry type: Text.
Validation Procedures:
4.2.13.1 Only one "Warranty/Disclaimer Statement" section is allowed.
4.2.13.2 The section title is the same as the section code displayName.

Xml code snippet:
```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144249" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Limitation of Warranty and Liability"/>
  <title>Limitation of Warranty and Liability</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
```

4.2.14 Marketing/Advertising Claims

Comprehensive numbered list of optional language used to market the product or make claims about the effectiveness or characteristics of the product. The Certifications and Seals subsection identifies third party seals or certifications displayed on the label and associated text (e.g., This certification does not imply enhanced safety or efficacy).

- If this section applies to the product, enter the appropriate text in this box.
- If this section does not apply to the product, leave the text box blank.

Reference: LRM Chapter 12

Entry type: Text.

Entry type: "*Certifications and Seals*" picklist selection.

Validation Procedures:
4.2.14.1 There is a Label or Marketing Claims section.
4.2.14.2 The section title is the same as the section code displayName.
4.2.14.3 Section code comes from 3852212.
4.2.14.4 There is subsection named as Certifications and Seals.
4.2.14.5 The Certifications and Seals section title is the same as the section code displayName.
4.2.14.6 Certification and Seals code comes from the list *Certifications and Seals*.
4.2.14.7 DisplayName matches the code.

4.2.14.8 If there is a Certification and Seals subsection, there is text associated
with the approval.

<u>Xml code snippet:</u>

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144194" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Marketing/Advertising Claims"/>
  <title>Marketing/Advertising Claims</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
  <component>
    <section ID="Section Link">
      <id root="Section UUID"/>
      <code code="3852212"
            codeSystem="2.16.840.1.113883.6.275.1"
            displayName="Certifications and Seals"/>
      <title>Certifications and Seals</title>
      <effectiveTime value="YYYYMMDD"/>
      <subject>
        <manufacturedProduct>
          <manufacturedProduct/>
          <subjectOf>
            <approval>
              <code code="Certifications and Seals code"
                    codeSystem="2.16.840.1.113883.6.275.1"
                    displayName="Certifications and Seals name"/>
              <text>Certifications and Seals text</text>
            </approval>
          </subjectOf>
          <!-- Additional Certifications and Seals -->
          <subjectOf>
            <approval>
              <code code="Certifications and Seals code"
                    codeSystem="2.16.840.1.113883.6.275.1"
                    displayName="Certifications and Seals name"/>
              <text>Certifications and Seals text</text>
            </approval>
          </subjectOf>
        </manufacturedProduct>
      </subject>
```

4.2.15 Additional Documentation and labeling

Note: This section is not implemented yet.
This label section is to provide an explanation of any additional documents or labeling
which is uploaded as a .pdf document and associated with the registration. If the uploaded
documents are part of the product labeling, the content must appear within the structured
master label. No new label content can appear in the uploaded associated labeling. For
example:
- Product Display Panels:
    - Base Label – the portion of the label affixed to the container
    - Booklet Cover – the first page of the label booklet which is inpermentally
      affixed to the product

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- Application Manual – label information which accompanies the product but is not affixed to the product
- Vial/Unit Packaging Labels – label information which is printed on individual units which are packaged together
- Supplemental Labels – proposed/accepted supplemental labels which are distributed at the point of sale with the product which provide expanded use patterns or specific instructions for geographic locations/application equipment/pests controlled or other variable
- If this section applies to the product, enter the appropriate text in this box.
- If this section does not apply to the product, leave the text box blank.
- Reference: LRM Chapter 18

Validation Procedures

4.2.15.1 There is an Additional Documentation and Labeling section.

4.2.15.2 The section title is the same as the section code displayName.

4.2.15.3 There are zero to many document or label attachment references.

4.2.15.4 Document or label attachment references must have a text element with mediaType and reference.

4.2.15.5 Reference value must be the file name for a valid document attachment.

4.2.15.6 File name extension matches the media type ".pdf".

XML Code Snippet:

```
<section ID="Section Link">
  <id root="Section UUID"/>
  <code code="3144228" codeSystem="2.16.840.1.113883.6.275.1"
        displayName="Additional Documentation and Labeling"/>
  <title>Additional Documentation and Labeling</title>
  <text/>
  <effectiveTime value="YYYYMMDD"/>
  <subject>
    <manufacturedProduct>
      <!-- Attached Documents / Labels -->
      <subjectOf>
        <document>
          <text mediaType="application/pdf">
            <reference value="20150304_5fa97bf5-28a2-48f1-8955-
f56012d296be.pdf"/>
          </text>
        </document>
      </subjectOf>
      <!-- Additional Documents -->
      <subjectOf>
        <document>
          <text mediaType="application/pdf">
            <reference value="20141215_4bca97bf5-28a2-48f1-8955-
f56012d296be.pdf"/>
          </text>
        </document>
      </subjectOf>
```

5 Use Index

The goal of the Use Index document is to capture and display the unique use patterns registered for each label in a queryable, tabular format that can easily be compared across registrations. It does this by translating the use patterns described using narrative in the Pesticide Labeling document and capturing them using combinations of discrete predefined picklist terms and value entries. The Use Index can then be used as a tool to review and assess the Pesticide Label registration.

This document captures data as terms from a picklists, and/or value unit combinations. If a picklist is used, the name of the picklist will be listed in the "Entry type" field of each subsection. The items in each picklist and their definitions are compiled on the SmartLabel website:

https://www.epa.gov/pesticide-registration/pesticide-smartlabel-pilot-documents

This document and the definitions it contains can be used as a reference when filling out the Use Index to aid the user in selecting the correct term. If a term to fit your needs cannot be found, please contact *SmartLabel@epa.gov*, for assistance determining the correct term. If an appropriate term cannot be found, a new term can be established and added to the vocabulary. Because new terms will likely be added on a semi-regular basis, please periodically refer to the SmartLabel website for the most current listing of vocabularies and definitions.

5.1 Document Information

This section provides basic information for the identity of the particular document, its type, title, date and versioning as a member of a document set.

5.1.1 Document Type

This provides information on the subject matter of the document. In this case the "Use Index" is selected.

Entry type: "Document type" picklist selection.

Validation Procedures:

5.1.1.1.1.1   Document type is "Use Index" (3810133).
5.1.1.1.1.2   Code comes from EPA "Document type" list.
5.1.1.1.1.3   Code system is 2.16.840.1.113883.6.275.1.
5.1.1.1.1.4   Display name matches the code.
5.1.1.1.1.5   If a document with the same set id was previously submitted then this document and the previous document are of the same type.

Xml Code Snippet:

```
<document xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
          xmlns="urn:hl7-org:v3"
          xsi:schemaLocation="urn:hl7-org:v3 SPL.xsd">

   <id root="{Document Id}"/>
```

```
<!-- Document Type -->
<code code="3810133"
      codeSystem="2.16.840.1.113883.6.275.1"
      displayName="Use Index"/>

<effectiveTime value="{Effective Date}"/>

<setId root="{Set Id}"/>
<versionNumber value="{Version Number}"/>
```

5.1.2   Author Information

This provides basic information about the business responsible for the product, including the company name and number.

- The *Company Name*, identifies the name of the organization registering the product using the company name registered with the agency that is associated with the company number entered below.

  Entry type: text

- The *Company Number* identifies the organization registering the product using EPA registered company numbers. These are identifiers with the root 2.16.840.1.113883.6.275.1 and an extension.

  Entry type: value

Validation Procedures:

5.1.2.1.1.1   There is an author element.
5.1.2.1.1.2   There are no other elements than id and name.
5.1.2.1.1.3   The company number is the 1-6 digit number assigned to the company by the EPA.
5.1.2.1.1.4   There is only one company name.

Xml Code Snippet:

```
Author information is used to identify the business responsible for the
product, represented here by the EPA registered Company Name and Company
number. The Company Name is the name registered with EPA, and the Company
number is the unique 1-6 digit number assigned to the company by the EPA
(product number is entered in another section)<document
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
        xmlns="urn:hl7-org:v3"
        xsi:schemaLocation="urn:hl7-org:v3 SPL.xsd">

    <!-- other header elements -->

    <author>
      <assignedEntity>
        <representedOrganization>
          <id root="2.16.840.1.113883.6.275.1"
              extension="{Company Number}"/>
          <name>{Company Name}</name>
        </representedOrganization>
```

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```
            </assignedEntity>
          </author>
```

5.2   SPL Body

5.2.1   Sections in General

The body of the Use Index document includes structured text (such as company name), structured values (such as percent active ingredient), and/or specific data elements from picklists (such as active ingredient).

Sections and subsections have id, title, and code. The Section Names list provides the codes used for sections and subsections.

Refer to Section 2.2 of this document for specific information about how each structured xml section is coded.

The following xml code snippet is a representative coding for a section in general.

Validation Procedures:

5.2.1.1.1.1   Section codes must come from the "Use Index Section Names" list.
5.2.1.1.1.2   Section codeSystem is as 2.16.840.1.113883.6.275.1.
5.2.1.1.1.3   Section code display name matches the code.
5.2.1.1.1.4   Section title is the same as the section display name.

Xml Code Snippet:

```
<document>
  ...
  <structuredBody>
    <component>
      <section>
       <!-- other elements -->
        <code code="{Section Code}"
codeSystem="2.16.840.1.113883.6.275.1"
            displayName="{Section DisplayName}">
        <title>Company Name</title>
        <effectiveTime value="{Creation Date}"/>
        <subject>
        <!-- data elements -->
        </subject>
        <component>
          <section>
            ...
```

5.2.2   Use Index Sections

The SPL Body sections of the Use Index are interpreted as a hierarchy. There are three main sections in the hierarchy; as depicted below:

- Product Level (describes the registration and the restrictions/limitations that apply to all use sites and methods of application).

- Use Site Level (describes the place that the pesticide is intended to be applied, and the restrictions/limitations that apply to all application methods at the site).

  - Scenario Level (describes the methods with which an application can be made to the site using a specified rate pattern, and the restrictions/limitations that apply to those application methods).

Information entered at a higher level applies to all levels that fall below it in the model. Thus, all information entered at the Product level applies to all Use Sites and all Scenarios; and information entered at the Use Site level applies to all Scenarios for that Use Site. Information must be entered only at the lowest level of differentiation, so as not to contradict information entered at higher levels (including rates and limitations). Entry of data for the same field at multiple levels will result in a validation error. Therefore, the entrant should give thought to where a given data element falls in the hierarchy before they extract information from the label.

The Use Index document contains only data elements. No sections within the Use Index document contain text or narrative. A skeletal XML snippet is shown below.

Validation Procedures:

5.2.2.1.1.1   There is one Product Level section per document.
5.2.2.1.1.2   There are one or more Site Level sections per document.
5.2.2.1.1.3   There are one or more Scenario Level sections per Site Level section.

Xml Code Snippet:

```
<?xml version="1.0" encoding="UTF-8"?>
<document xmlns="urn:hl7-org:v3"
          xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
          xsi:schemaLocation="urn:hl7-org:v3 SPL.xsd">
   <id root="{Document Id}"/>
   <code code="3810133"
         codeSystem="2.16.840.1.113883.6.275.1"
         displayName="Use Index"/>
   <!-- other elements -->
   <component>
      <structuredBody>
         <component>
            <section ID="{Section Link}">
               <id root="{Section Id}"/>
               <code code="3810084"
codeSystem="2.16.840.1.113883.6.275.1"
                     displayName="Product Level"/>
               <title>Product Level</title>

               <component>
                  <section ID="{Section Link}">
                     <id root="{Section Id}"/>
                     <code code="3810085"
codeSystem="2.16.840.1.113883.6.275.1"
```

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```xml
                              displayName="Product Identification"/>
                         <title>Product Identification</title>
                         <!-- other elements -->
                    </section>
                </component>

                <component>
                    <section ID="{Section Link}">
                         <id root="{Section Id}"/>
                         <code code="3810086"
codeSystem="2.16.840.1.113883.6.275.1"
                              displayName="Product Level Use
Restrictions/Limitations"/>
                         <title>Product Level Use
Restrictions/Limitations</title>
                         <!-- other elements -->
                    </section>
                </component>
            </section>
        </component>

        <component>
            <section ID="{Section Link}">
                <id root="{Section Id}"/>
                <code code="3810087"
codeSystem="2.16.840.1.113883.6.275.1"
                     displayName="Site Level"/>
                <title>Site Level</title>

                <component>
                    <section ID="{Section Link}">
                         <id root="{Section Id}"/>
                         <code code="3810088"
codeSystem="2.16.840.1.113883.6.275.1"
                              displayName="Use Site Attributes"/>
                         <title>Use Site Attributes</title>
                         <!-- other elements -->
                    </section>
                </component>

                <component>
                    <section ID="{Section Link}">
                         <id root="{Section Id}"/>
                         <code code="3810089"
codeSystem="2.16.840.1.113883.6.275.1"
                              displayName="Use Site Yearly Rate"/>
                         <title>Use Site Yearly Rate</title>
                         <!-- other elements -->
                    </section>
                </component>

                <component>
                    <section ID="{Section Link}">
                         <id root="{Section Id}"/>
                         <code code="3810090"
codeSystem="2.16.840.1.113883.6.275.1"
                              displayName="Use Site Level
Restrictions/Limitations"/>
                         <title>Use Site Level
Restrictions/Limitations</title>
                         <!-- other elements -->
                    </section>
```

```
                </component>

                <component>
                    <section ID="{Section Link}">
                        <id root="{Section Id}"/>
                        <code code="3810091"
codeSystem="2.16.840.1.113883.6.275.1"
                                displayName="Scenario Level"/>
                        <title>Scenario Level</title>

                        <component>
                            <section ID="{Section Link}">
                                <id root="{Section Id}"/>
                                <code code="3810092"
codeSystem="2.16.840.1.113883.6.275.1"
                                        displayName="Scenario Rate"/>
                                <title>Scenario Rate</title>
                                <!-- other elements -->
                            </section>
                        </component>

                        <component>
                            <section ID="{Section Link}">
                                <id root="{Section Id}"/>
                                <code code="3810093"
codeSystem="2.16.840.1.113883.6.275.1"
                                        displayName="Scenario Attributes"/>
                                <title>Scenario Attributes</title>
                                <!-- other elements -->
                            </section>
                        </component>

                        <component>
                            <section ID="{Section Link}">
                                <id root="{Section Id}"/>
                                <code code="3810094"
codeSystem="2.16.840.1.113883.6.275.1"
                                        displayName="Use Scenario Level
Restrictions/Limitations"/>
                                <title>Use Scenario Level
Restrictions/Limitations</title>
                                <!-- other elements -->
                            </component>
                        </section>
                    </component>
                </section>
            </component>
        </structuredBody>
    </component>
</document>
```

5.2.3 Product Level

The "Product Level" section is a header section to contain the subsections Product Identification and Product Level Use Restrictions/Limitations. Information entered in the Product Level subsections applies to all Use Sites and Scenarios.

Validation Procedures:

5.2.3.1.1.1   There is one "Product Level" section.
5.2.3.1.1.2   The section title is the same as the section code displayName.

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5.2.3.1.1.3   The section link is optional.

5.2.3.1.1.4   If the section link is provided then the section link is a unique string within the document.

5.2.3.1.1.5   The section id is a unique UUID within the document.

Xml Code Snippet:

```
<component>
   <section ID="{Section Link}">
      <id root="{Section Id}"/>
      <code code="3810084" codeSystem="2.16.840.1.113883.6.275.1"
            displayName="Product Level"/>
      <title>Product Level</title>
```

5.2.3.2   Product Identification

This subsection identifies the product and is used to link this document with the "End-Use Pesticide Label" document for the same product. It provides basic information to identify and characterize the particular product (including registration number, active ingredients and their percentages, and other physical characteristics of certain types of product).

Validation Procedures:

5.2.3.2.1.1   There is one "Product Identification" section.

5.2.3.2.1.2   The section title is the same as the section code displayName.

5.2.3.2.1.3   The section link is optional.

5.2.3.2.1.4   If the section link is provided then the section link is a unique string within the document.

5.2.3.2.1.5   The section id is a unique UUID within the document.

Xml Code Snippet:

```
<component>
   <section ID="{Section Link}">
      <id root="{Section Id}"/>
      <code code="3810085" codeSystem="2.16.840.1.113883.6.275.1"
            displayName="Product Identification"/>
      <title>Product Identification</title>
```

5.2.3.2.2 Product Number

This captures the unique 1-5 digit number assigned to the product by the EPA. This number is combined with the EPA Company Number (previously entered in the Author section) to form a unique identifier for each registered pesticide product, known as the EPA Registration Number.

Entry type: value

<u>Validation Procedures:</u>

5.2.3.2.2.1   The Product Number is required and the code cannot be blank.

5.2.3.2.2.2   The Product Number is the number assigned to the product and does not include the company number (the company number is captured in the author element of the Header section).

<u>Xml Code Snippet:</u>

```
<title>Product Identification</title>
<subject>
   <manufacturedProduct>
      <manufacturedProduct>

         <!-- Product Number -->
         <code code="{Product Number}""/>
```

5.2.3.2.3 *Active Ingredient(s)* (+)

Identifies and characterizes the active ingredients contained in the product, including: a listing of active ingredient(s) and their respective nominal concentrations (expressed as a percentage); as well as any information regarding concentrations of equivalence of the active ingredients, identified in this document as Factoring Term (e.g. elemental metallics, acid equivalents, or other moieties).

- The **Percent Active Ingredient** is a number describing the amount of active ingredient per the total amount of the formulated product.
- Optionally, a **Factoring Term** value can be specified for certain types of chemicals. The Factoring Term value is a number describing the amount of a formulation that theoretically could be converted back to the corresponding or parent active ingredient per the total weight of the formulated product.

Multiple Active Ingredients can be entered.

<u>Entry type:</u> *"SRS Systematic Name"* selection and value.

<u>Validation Procedures:</u>

5.2.3.2.3.1   There are one or more active ingredients.

5.2.3.2.3.2   The percent active ingredient unit code is "3627136" and displayName is '%'.

5.2.3.2.3.3   The percent factoring term value is a number.

5.2.3.2.3.4   The factoring term unit's unit code is "3627136" and displayName is '%'.

<u>Xml Code Snippet:</u>

```
<title>Product Identification</title>
<subject>
   <manufacturedProduct>
      <manufacturedProduct>
```

```
            <!-- other elements -->

            <!-- (1..*) Active Ingredient -->
            <ingredient classCode="ACTIB">
              <quantity>
                <numerator xsi:type="PQ" nullFlavor="OTH">
                  <translation code="3627136"
                         codeSystem="2.16.840.1.113883.6.275.1"
                         displayName="%" value="{Percent Value}"/>
                </numerator>
                <denominator value="1"/>
              </quantity>
              <ingredientSubstance>
                <code code="SRS Internal Tracking Number"
                      codeSystem="2.16.840.1.113883.6.275"/>
                <name>SRS Systematic Name</name>

                <!-- Percent Factoring Term -->
                <activeMoiety>
                  <quantity>
                    <numerator xsi:type="PQ" nullFlavor="OTH">
                      <translation code="3627136"
                               codeSystem="2.16.840.1.113883.6.275.1"
                               displayName="%" value="{Percent Value}"/>
                    </numerator>
                    <denominator value="1"/>
                  </quantity>
                  <activeMoiety>
                    <code code="{Molecule Code}"
                          codeSystem="2.16.840.1.113883.6.275""/>
                    <name>{Molecule Name}</name>
                  </activeMoiety>
                </activeMoiety>
              </ingredientSubstance>
            </ingredient>
```

5.2.3.2.4 Product Density

Identifies the weight of active ingredient per volume/mass of product. Both values and units are entered here.

Entry type: value unit, per value unit.

Validation Procedures:

5.2.3.2.4.1 Product density is optional.
5.2.3.2.4.2 Mass quantity is a number.
5.2.3.2.4.3 Mass units must be Standard Weight / Mass units.
5.2.3.2.4.4 Volume quantity is a number.
5.2.3.2.4.5 Volume units must be Standard Volume / Capacity.

Xml Code Snippet:

```
<title>Product Identification</title>
<subject>
   <manufacturedProduct>

      <!-- other elements -->
```

```
      <!-- Product Density -->
      <subjectOf>
         <characteristic>
            <code code="1005310" codeSystem="2.16.840.1.113883.6.275.1"
                  displayName="Product Density"/>

            <value xsi:type="RTO_PQ_PQ">
               <numerator xsi:type="PQ" nullFlavor="OTH">
                  <translation value="{Mass Quantity}"
                               displayName="{Unit DisplayName"
                               code="{Unit Code}"
                               codeSystem="2.16.840.1.113883.6.275.1"/>
               </numerator>
               <denominator xsi:type="PQ" nullFlavor="OTH">
                  <translation value="{Volume Quantity}"
                               displayName="{Unit DisplayName"
                               code="{Unit Code}"
                               codeSystem="2.16.840.1.113883.6.275.1"/>
               </denominator>
            </value>

         </characteristic>
      </subjectOf>
```

5.2.3.2.5 *Mass Active Ingredient per Miscellaneous Application Unit*

The mass active ingredient per miscellaneous application unit identifies the mass of product per each miscellaneous application unit as deployed (e.g. mass of active ingredient per: bait station, per ear tag, per water soluble package, etc.). This information must be supplied if miscellaneous application units are used in any of the rate sections at the site or scenario level (s). Both values and units are entered.

See unit definitions in the SmartLabel Vocabulary Guide for a complete listing of Miscellaneous Application Units.

Entry type: value unit, per value unit.

Validation Procedures:
5.2.3.2.5.1 Mass active ingredient per miscellaneous application unit is required if miscellaneous application units are used in any of the rate sections at the site or scenario level(s).
5.2.3.2.5.2 Mass active ingredient numerator and denominator values are numbers.
5.2.3.2.5.3 Numerator units must be Standard Weight / Mass.
5.2.3.2.5.4 Denominator units must be Miscellaneous Application.

Xml Code Snippet:

```
<title>Product Identification</title>
<subject>
   <manufacturedProduct>

      <!-- other elements -->

      <!-- Mass A.I. per Miscellaneous Application Unit -->
```

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```
        <subjectOf>
           <characteristic>
              <code code="1005311" codeSystem="2.16.840.1.113883.6.275.1"
                    displayName="Mass A.I. per Miscellaneous Application
Unit"/>

              <value xsi:type="RTO_PQ_PQ">
                <numerator xsi:type="PQ" nullFlavor="OTH">
                   <translation value="{Mass Active Ingredient}"
                              displayName="{Unit DisplayName" code="{Unit
Code}"
                              codeSystem="2.16.840.1.113883.6.275.1"/>
                </numerator>
                <denominator xsi:type="PQ" nullFlavor="OTH">
                   <translation value="{Misc Application Value}"
                              displayName="{Unit DisplayName" code="{Unit
Code}"
                              codeSystem="2.16.840.1.113883.6.275.1"/>
                </denominator>
              </value>
           </characteristic>
        </subjectOf>
```

5.2.3.3 Product Level Use Restrictions/Limitations

Identifies only Product Level Restrictions/Limitations, which are applicable to all use sites and all scenarios. If a restriction/limitation differs between sites, it should be entered only at the site level. If a restriction/limitation differs between scenarios of a given site, it should be entered only at the scenario level. Entry of data for the same field at multiple levels will result in a validation error. Restrictions/Limitations should only be recorded in the Use Index if the label explicitly restricts or limits the identified data element in legally enforceable language. Statements that include terms like "should" or "for best results" are not legally enforceable, and should not be recorded.

Multiple entries are possible for many Restrictions/Limitations. In this document, data elements that may have multiple entries are marked with a (+) after their title. Additionally, the validation rules for each element indicate if entry is optional and the number of entries that can be entered.

Leaving a restriction blank indicates that there is no restriction at this level.

Validation Procedures:

5.2.3.3.1.1 There is one "Product Level Use Restrictions/Limitations" section.
5.2.3.3.1.2 The section title is the same as the section code displayName.
5.2.3.3.1.3 The section link is optional.
5.2.3.3.1.4 If the section link is provided then the section link is a unique string within the document.
5.2.3.3.1.5 The section id is a unique UUID within the document.

Xml Code Snippet:

```
<component>
   <section ID="{Section Link}">
```

```
        <id root="{Section Id}"/>
        <code code="381086" codeSystem="2.16.840.1.113883.6.275.1"
              displayName="Product Level Use Restrictions/Limitations"/>
        <title>Product Level Use Restrictions/Limitations</title>
```

5.2.3.3.2 *Geographic Area Allowed* (+)

Identifies restrictions associated with geographic location, at the state and county level, by listing areas where application *is* allowed. This is a required field at either the Product, Site, or Scenario level for each method. If applications are not restricted to any particular geographic area, select "United States". If application is not allowed in a particular area, select all areas except the prohibited area.

Entry type: "*Geographic Area*" picklist selection.

Validation Procedures:

5.2.3.3.2.1   There is at least one Geographic Area for each scenario. The scenario is considered to have Geographic Area if it is provided at the Product, Site, or Scenario levels.

5.2.3.3.2.2   If Geographic Area is provided at any Site or Scenario levels, there should be no Geographic area provided at the Product level.

5.2.3.3.2.3   Code is from the list "*Geographic Area*".

5.2.3.3.2.4   DisplayName matches the code.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (1..*) Geographic Area Allowed -->
            <component>
               <requirement>
                  <code code="1005202"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Geographic Area">
                     <qualifier xsi:type="CR">
                        <value code="{Geographic Area Code}"
                                codeSystem="2.16.840.1.113883.6.275.1"
                                displayName="{Geographic Area
DisplayName}"/>
                     </qualifier>
                  </code>
               </requirement>
            </component>
```

5.2.3.3.3 *Food Site Relationship*

Identifies if application(s) are intended to come in contact with food or feed, which may indicate the need for a pesticide tolerance or a certain kind of regulatory risk assessment. This information is required for agricultural crops (at either the Product, Site, or Scenario

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level for each method) to establish whether crops may be used as food or feed (Bearing), or may not be used as food or feed (Non-Bearing/Dormant, Grown for Seed). If the product labeling for non-agricultural sites explicitly prohibits applications that may contact food or feed, No Food/Feed Contact should be selected (see definitions in the SmartLabel Vocabulary Guide for further guidance).

Entry type: "*Use Site Food Relationship*" picklist selection.

Validation Procedures:

5.2.3.3.3.1   There is one Food Site Relationship for each scenario. The Scenario is considered to have a Food Site Relationship if it is provided at the Product, Site, or Scenario Levels.

5.2.3.3.3.2   If Food Site Relationship is provided at any Site or Scenario levels, there should be no Food Site Relationship provided at the product level.

5.2.3.3.3.3   Code is from the list *Use Site Food Relationship*.

5.2.3.3.3.4   DisplayName matches the code.

Xml Code Snippet:

```xml
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

           <!-- other elements -->

           <!-- (1..1) Food Site Relationship -->
           <component>
              <requirement>
                 <code code="1005021"
codeSystem="2.16.840.1.113883.6.275.1"
                       displayName="Use Site Food Relationship">
                    <qualifier xsi:type="CR">
                       <value code="{Use Site Food Relationship Code}"
                               codeSystem="2.16.840.1.113883.6.275.1"
                               displayName="{Use Site Food Relationship
DisplayName}"/>
                    </qualifier>
                 </code>
              </requirement>
           </component>
```

5.2.3.3.4 Restriction Maximum Active Ingredient Rate Across Products

Identifies the maximum amount of active ingredient (or in some cases the maximum amount of a chemical class) that may be applied to a given area across products that contain the same active ingredient (or a.i. class). This restriction is often stated on labels as "Do not apply more than [x amount] of product per [year or crop cycle] from this or any other product containing this active ingredient".

Entry type: value unit, per value unit, per "*Application Rate Measurement Period"* picklist selection.

Validation Procedures:

5.2.3.3.4.1   There are zero or one Restriction Maximum Active Ingredient Rate Across Products substanceAdministrations.

5.2.3.3.4.2   If Maximum Active Ingredient Rate Across Products substanceAdministrations is provided at the Site or Scenario Level, then there should not also be a Maximum Active Ingredient Rate Across Products substance Administrations provided at the Product level.

5.2.3.3.4.3   The Maximum Rate is a number.

5.2.3.3.4.4   Numerator units must be one of the following:

- Standard Weight / Mass
- Standard Volume / Capacity
- Miscellaneous Application Unit
- Concentration
- Non-Standard Volume / Capacity

5.2.3.3.4.5   Denominator units must be one of the following:

- Standard Area
- Standard Length
- Standard Weight / Mass
- Standard Volume / Capacity
- Time
- Blank (if numerator is Concentration)
- Non-Standard Volume / Capacity
- Non-standard - Target (with acreage rate limit)
- Non-Standard Weight / Mass
- Miscellaneous – Target

5.2.3.3.4.6   Method code is from the list *Application Rate Measurement Period*.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Restriction Max A.I. Rate Across Products -->
            <component>
               <substanceAdministration>
                  <subjectOf>
                     <characteristic>
                        <code code="1005323"
                              codeSystem="2.16.840.1.113883.6.275.1"
                              displayName="Max A.I. Rate Across Products"/>
                        <value xsi:type="RTO_PQ_PQ">
```

```
                    <numerator xsi:type="PQ" nullFlavor="OTH">
                      <translation value="{Maximum Rate}"
                            displayName="{Unit DisplayName"
                            code="{Unit Code}"
                            codeSystem="2.16.840.1.113883.6.275.1"/>
                    </numerator>
                    <denominator xsi:type="PQ" nullFlavor="OTH">
                      <translation value="{Per Quantity}"
                            displayName="{Unit DisplayName"
                            code="{Unit Code}"
                            codeSystem="2.16.840.1.113883.6.275.1"/>
                    </denominator>
                  </value>
                  <methodCode code="{Method Code}"
                        codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="{Method DisplayName}"/>
                </characteristic>
              </subjectOf>
            </substanceAdministration>
          </component>
```

5.2.3.3.5 *Rotational Crop*

Identifies if any rotational crop restrictions apply to this specific product. This is a presence/absence indicator. If any restrictions to rotation plantings appear on the label (including what may be planted following the current crop, or the length of time that must pass before a crop can be planted in the area), then Rotational Crop should be selected.

Entry type: presence/absence selection (absence selected as default).

Validation Procedures:

5.2.3.3.5.1   There is zero to one Rotational Crop requirements.
5.2.3.3.5.2   If Rotational Crop is provided at the Site or Scenario Level, then there should not also be Rotational Crop provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Rotational Crop -->
            <component>
               <requirement>
                  <code code="1005337"
codeSystem="2.16.840.1.113883.6.275.1"
                       displayName="Rotational Crop"/>
               </requirement>
            </component>
```

5.2.3.3.6 *Applicator Class Restrictions* (+)

Identifies those individuals or groups of individuals who are allowed to apply the product, if only certain classes of applicator are allowed. The existence of an Application Class requirement(s), by definition, indicates all other applicators are restricted from using the product.

Entry type: "*Applicator Class Restrictions*" picklist selection.

Validation Procedures:

5.2.3.3.6.1   Code is from the list *Applicator Class Restrictions*.
5.2.3.3.6.2   DisplayName matches the code.
5.2.3.3.6.3   There is zero to many Applicator Class Restrictions.
5.2.3.3.6.4   If Applicator Class Restriction(s) is/are provided at the Site or Scenario Level, then it should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Applicator Class Restrictions -->
            <component>
               <requirement>
                  <code code="1004442"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Applicator Class Restrictions">
                     <qualifier xsi:type="CR">
                        <value code="{Applicator Class Restriction}"
                                codeSystem="2.16.840.1.113883.6.275.1"
                                displayName="{Applicator Class
Restriction DisplayName}"/>
                     </qualifier>
                  </code>
               </requirement>
            </component>
```

5.2.3.3.7 *Personal Protective Equipment (PPE) / Engineering Control* (+)

This indicates the PPE and/or engineering controls are required for use of the product. Information captured here is not limited to information in the Agricultural Use box on the label. It is intended to capture requirements for PPE/Engineering Controls that appear anywhere on the label.

Entry type: "*Personal Protective Equipment (PPE)/Engineering Control*" picklist selection.

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Validation Procedures:

5.2.3.3.7.1   There is zero to many PPE/Engineering Control requirements.

5.2.3.3.7.2   If PPE/Engineering Control(s) is/are provided at the Site or Scenario Level, then it should not also be provided at the Product level.

5.2.3.3.7.3   Code is from the list *Personal Protective Equipment (PPE)/Engineering Control*.

5.2.3.3.7.4   DisplayName matches the code

Xml Code Snippet:

```xml
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) PPE/Engineering control -->
            <component>
               <requirement>
                  <code code="1005024"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="PPE/Engineering Control">
                     <qualifier xsi:type="CR">
                        <value code="{PPE/Engineering Control Code}"
                               codeSystem="2.16.840.1.113883.6.275.1"
                               displayName="{PPE/Engineering Control
DisplayName}"/>
                     </qualifier>
                  </code>
               </requirement>
            </component>
```

5.2.3.3.8 *Restricted Entry Interval (REI)*

Identifies the minimum period of time after a pesticide application when entry into the treated area is restricted. Includes WPS and non-WPS re-entry intervals.

Entry type: value unit

Validation Procedures:

5.2.3.3.8.1   There is zero to one Restricted Entry Interval requirements.

5.2.3.3.8.2   If Restricted Entry Interval is provided at the Site or Scenario Level, then it should not also be provided at the Product level.

5.2.3.3.8.3   The value of sequenceNumber must be 3.

5.2.3.3.8.4   The Period of Time is a number.

5.2.3.3.8.5   Units must be time units.

Xml Code Snippet:

```xml
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
```

```
    <substanceAdministration>
       <componentOf>
          <protocol>

             <!-- other elements -->

             <!-- (0..1) REI -->
             <component>
                <!-- after application -->
                <sequenceNumber value="3"/>

                <requirement>
                   <code code="1005325"
codeSystem="2.16.840.1.113883.6.275.1"
                         displayName="Minimum period of time before worker
re-entry"/>
                   <effectiveTime xsi:type="IVL_TS">
                     <width xsi:type="PQ" nullFlavor="OTH">
                       <translation value="{Period of time value}"
                              displayName="{Unit DisplayName}"
                              code="{Unit Code}"
                              codeSystem="2.16.840.1.113883.6.275.1"/>
                     </width>
                   </effectiveTime>
                </requirement>
             </component>
          </component>
```

5.2.3.3.9 *Minimum Retreatment Interval (MRI)*

Identifies the minimum period of time after an application that must pass before the product can be reapplied to the same area or target.

Entry type: value unit

Validation Procedures:

5.2.3.3.9.1   There is zero to one Minimum Retreatment Interval requirements.
5.2.3.3.9.2   The value of sequenceNumber must be 3.
5.2.3.3.9.3   The Minimum Retreatment Interval is a number.
5.2.3.3.9.4   Units must be time units.
5.2.3.3.9.5   Required if more than one application is allowed, or if the single rate is not equal to the crop cycle/yearly rate.
5.2.3.3.9.6   If Minimum Retreatment Interval is provided at the Site or Scenario Level, then it should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

           <!-- other elements -->

           <!-- (0..1) MRI -->
           <component>
              <!-- after application -->
```

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```
                    <sequenceNumber value="3"/>

                    <requirement>
                       <code code="1005326"
                             codeSystem="2.16.840.1.113883.6.275.1"
                             displayName="Minimum period of time before re-
application"/>

                       <effectiveTime xsi:type="IVL_TS">
                          <width xsi:type="PQ" nullFlavor="OTH">
                             <translation value="{Minimum period of time}"
                                     displayName="{Unit DisplayName}"
                                     code="{Unit Code}"
                                     codeSystem="2.16.840.1.113883.6.275.1"/>
                          </width>
                       </effectiveTime>
                    </requirement>
                 </component>
```

5.2.3.3.10   *Pre-Harvest Interval (PHI)* (+)

Identifies the minimum period of time that must pass after an application before crop/commodity harvest. This data element may be blank if the final application is restricted to occur at or before a crop growth stage that is typically 30 days or more before harvest.

Entry type: "*Pre-Harvest Interval (PHI) Category*" picklist selection, and value unit.

Validation Procedures:

5.2.3.3.10.1 There is zero to many Pre-Harvest Interval requirements.
5.2.3.3.10.2 The sequenceNumber value is 3.
5.2.3.3.10.3 Code is from the list *Pre-Harvest Interval (PHI) Category*.
5.2.3.3.10.4 DisplayName matches the code.
5.2.3.3.10.5 The Pre-Harvest interval is a number.
5.2.3.3.10.6 Units must be time units.
5.2.3.3.10.7 If Pre-Harvest Interval is provided at the Site or Scenario Level, then it should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) PHI -->
            <component>
               <!-- after application -->
               <sequenceNumber value="3"/>
```

```
                <requirement>
                  <code code="1005028"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="PHI Category">
                    <qualifier xsi:type="CR">
                      <value code="{PHI Category Code}"
                                codeSystem="2.16.840.1.113883.6.275.1"
                                displayName="{PHI Category
DisplayName}"/>
                    </qualifier>
                  </code>

                  <effectiveTime xsi:type="IVL_TS">
                    <width xsi:type="PQ" nullFlavor="OTH">
                      <translation value="{PHI Value}"
                                  code="{Unit Code}"
                                  codeSystem="2.16.840.1.113883.6.275.1"
                                  displayName="{Unit DisplayName}"/>
                    </width>
                  </effectiveTime>
                </requirement>

              </component>
```

5.2.3.3.11   *Pre-Grazing Interval (PGI)/Pre-Feeding Interval (PFI)* (+)

Identifies the minimum period of time that must pass after an application before an identified group of animals may graze in treated areas, or may be fed treated material.

Entry type: "*Pre-Grazing Interval (PGI)/Pre-Feeding Interval (PFI) Category*" picklist selection, and value unit.

Validation Procedures:

5.2.3.3.11.1 There is zero to many Pre-Grazing Intervals requirements.
5.2.3.3.11.2 The sequenceNumber value is 3.
5.2.3.3.11.3 Code is from the list *Pre-Grazing Interval (PGI)/Pre-Feeding Interval (PFI) Category*.
5.2.3.3.11.4 DisplayName matches the code.
5.2.3.3.11.5 The Pre-Grazing interval is a number.
5.2.3.3.11.6 Units must be time units.
5.2.3.3.11.7 If Pre-Grazing Interval (PGI)/*Pre-Feeding Interval (PFI)* is provided at the Site or Scenario Level, then it should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
    <substanceAdministration>
        <componentOf>
            <protocol>

                <!-- other elements -->

                <!-- (0..*) PGI -->
                <component>
```

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```
                  <!-- after application -->
                  <sequenceNumber value="3"/>

                  <requirement>
                     <code code="1005026"
codeSystem="2.16.840.1.113883.6.275.1"
                           displayName="PGI Category">
                        <qualifier xsi:type="CR">
                           <value code="{PGI Category Code}"
                                  codeSystem="2.16.840.1.113883.6.275.1"
                                  displayName="{PGI Category
DisplayName}"/>
                        </qualifier>
                     </code>

                     <effectiveTime xsi:type="IVL_TS">
                        <width xsi:type="PQ" nullFlavor="OTH">
                           <translation value="{Pre-Grazing Interval}"
                                        code="{Unit Code}"
                                        codeSystem="2.16.840.1.113883.6.275.1"
                                        displayName="{Unit DisplayName}"/>
                        </width>
                     </effectiveTime>
                  </requirement>
               </component>
```

5.2.3.3.12   *Pre-Slaughter Interval (PSI)* (+)

Identifies the minimum period of time after an application that must pass before an
identified group of animals that have contacted the product can be slaughtered for food or
feed.

Entry type: "*Pre-Slaughter Interval (PSI) Category*" picklist selection, and value
unit.

Validation Procedures:

5.2.3.3.12.1 There is zero to many Pre-Slaughter Interval requirements.
5.2.3.3.12.2 The sequenceNumber value is 3.
5.2.3.3.12.3 Code is from the list *Pre-Slaughter Interval (PSI) Category*.
5.2.3.3.12.4 DisplayName matches the code.
5.2.3.3.12.5 Pre-Slaughter interval is a number.
5.2.3.3.12.6 If Pre-Slaughter Interval is provided at the Site or Scenario Level,
              then it should not also be provided at the Product level.
5.2.3.3.12.7 Units must be time units.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->
```

```
            <!-- (0..*) PSI -->
            <component>
               <!-- after application -->
               <sequenceNumber value="3"/>

               <requirement>
                  <code code="1005027"
codeSystem="2.16.840.1.113883.6.275.1"
                         displayName="PSI Category">
                     <qualifier xsi:type="CR">
                        <value code="{PSI Category Code}"
                                 codeSystem="2.16.840.1.113883.6.275.1"
                                 displayName="{PSI Category
DisplayName}"/>
                     </qualifier>
                  </code>

                  <effectiveTime xsi:type="IVL_TS">
                     <width xsi:type="PQ" nullFlavor="OTH">
                        <translation value="{Pre-Slaughter Interval}"
                                      code="{Unit Code}"
                                      codeSystem="2.16.840.1.113883.6.275.1"
                                      displayName="{Unit DisplayName}"/>
                     </width>
                  </effectiveTime>
               </requirement>
            </component>
```

5.2.3.3.13   *Buffer Zone* (+)

Identifies the minimum distance that is required between the area where a product is
applied and the specific area to be protected from the pesticide application.

> **Entry type:** "*Buffered Area*" picklist selection, and value unit.

> **Validation Procedures:**
> 5.2.3.3.13.1 There is zero to many Buffer Area preconditions.
> 5.2.3.3.13.2 The checkPoint code is 'T'.
> 5.2.3.3.13.3 Code is from the list *Buffered Area*.
> 5.2.3.3.13.4 DisplayName matches the code.
> 5.2.3.3.13.5 The Buffered Area value is a number.
> 5.2.3.3.13.6 Units must be Standard Length units.
> 5.2.3.3.13.7 If Buffer Zone is provided at the Site or Scenario Level, then it
> should not also be provided at the Product level.

> **Xml Code Snippet:**

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Buffer Zone -->
```

```
            <precondition>
               <!-- observation must hold true throughout application -->
               <checkpointCode code="T"/>

                <observationCriterion>
                   <code code="1004980"
codeSystem="2.16.840.1.113883.6.275.1"
                         displayName="Buffered Area">
                      <qualifier xsi:type="CR">
                         <value code="{Buffered Area Code}"
                                codeSystem="2.16.840.1.113883.6.275.1"
                                displayName="{Buffered Area
DisplayName}" />
                      </qualifier>
                   </code>

                   <value xsi:type="PQ" nullFlavor="OTH">
                     <translation value="{Buffered Area value}"
                            displayName="{Unit DisplayName}"
                            code="{Unit Code}"
                            codeSystem="2.16.840.1.113883.6.275.1"/>
                   </value>

                </observationCriterion>
            </precondition>
```

5.2.3.3.14   *Max Release Height*

Identifies the maximum distance between the point of release from the application equipment and the top of crop or ground.

   Entry type: value unit.

   Validation Procedures:
   5.2.3.3.14.1 There is zero to one Maximum Release Height precondition.
   5.2.3.3.14.2 The checkPoint code is 'T'.
   5.2.3.3.14.3 The Release Height is a number.
   5.2.3.3.14.4 Units must be Standard Length units.
   5.2.3.3.14.5 If Max Release height Precondition is provided at the Site or
                Scenario Level, then it should not also be provided at the Product
                level.

   Xml Code Snippet:
```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Max Release Height -->
            <precondition>
               <!-- observation must hold true throughout application -->
               <checkpointCode code="T"/>
```

```
                    <observationCriterion>
                       <code code="1005327"
codeSystem="2.16.840.1.113883.6.275.1"
                          displayName="Release Height"/>

                       <value xsi:type="PQ" nullFlavor="OTH">
                          <translation value="{Release Height}"
                                 displayName="{Unit DisplayName}"
                                 code="{Unit Code}"
                                 codeSystem="2.16.840.1.113883.6.275.1"/>
                       </value>

                    </observationCriterion>
                 </precondition>
```

5.2.3.3.15   Max Wind Speed

Identifies the maximum wind speed allowed during application.

Entry type: value unit.

Validation Procedures:

5.2.3.3.15.1 There is zero to one Maximum Wind Speed precondition.
5.2.3.3.15.2 The checkPoint code is 'T'.
5.2.3.3.15.3 The Wind speed is a number.
5.2.3.3.15.4 Units must be speed units.
5.2.3.3.15.5 If Max Wind Speed is provided at the Site or Scenario Level, then it
              should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Max Wind Speed -->
            <precondition>
               <!-- observation must hold true throughout application -->
               <checkpointCode code="T"/>

               <observationCriterion>

                  <code code="1005328"
codeSystem="2.16.840.1.113883.6.275.1"
                          displayName="Windspeed"/>

                  <value xsi:type="PQ" nullFlavor="OTH">
                     <translation value="{Wind Speed}"
                            displayName="{Unit DisplayName}"
                            code="{Unit Code}"
                            codeSystem="2.16.840.1.113883.6.275.1"/>
                  </value>
```

```
                    </observationCriterion>
                </precondition>
```

5.2.3.3.16   *Temperature Range at Application*

Identifies the minimum and maximum temperatures at which application(s) may be made.

Entry type: value unit, value unit.

Validation Procedures:

5.2.3.3.16.1 There is zero to one Temperature at Application preconditions.
5.2.3.3.16.2 The checkPoint code is 'B'.
5.2.3.3.16.3 The Minimum Temperature is a number.
5.2.3.3.16.4 The Maximum Temperature is a number.
5.2.3.3.16.5 The Minimum and Maximum Temperature units must be Temperature Units.
5.2.3.3.16.6 If Temperature Range at Application is provided at the Site or Scenario Level, then it should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Temperature Range at Application -->
            <precondition>
               <!-- observation checked before application -->
               <checkpointCode code="B"/>

               <observationCriterion>
                  <code code="1005330"
codeSystem="2.16.840.1.113883.6.275.1"
                     displayName="Temperature Range at Application"/>

                 <value xsi:type="IVL_PQ">
                   <low xsi:type="IVXB_PQ" nullFlavor="OTH">
                     <translation value="{Minimum Temperature}"
                          displayName="{Unit DisplayName}"
                          code="{Unit Code}"
                          codeSystem="2.16.840.1.113883.6.275.1"/>
                   </low>
                   <high xsi:type="IVXB_PQ" nullFlavor="OTH">
                     <translation value="{Maximum Temperature}"
                          displayName="{Unit DisplayName}"
                          code="{Unit Code}"
                          codeSystem="2.16.840.1.113883.6.275.1"/>
                   </high>
```

```
                    </value>
                </observationCriterion>
            </precondition>
```

5.2.3.3.17   *ASABE Droplet Size* (+)

Identifies restrictions associated with the application droplet size according to the ASABE 572 standard. Droplet sizes that are acceptable for application should be selected. This must be entered for broadcast applications using aerial or ground equipment.

Entry type: "*ASABE Droplet Size*" picklist selection, and value unit.

Validation Procedures:
5.2.3.3.17.1 There is zero to many ASABE requirements.
5.2.3.3.17.2 Required for Type = 'broadcast', Form as Applied = 'liquid formations' and Application Equipment = 'Aerial' or 'Groundboom'.
5.2.3.3.17.3 Code is from the list *ASABE Droplet Size*.
5.2.3.3.17.4 DisplayName matches the code.
5.2.3.3.17.5 If ASABE Droplet Size is provided at the Site or Scenario Level, then it should not also be provided at the Product level.

Xml Code Snippet:
```xml
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) ASABE Droplet Size -->
            <component>
               <requirement>
                  <code code="1004962"
codeSystem="2.16.840.1.113883.6.275.1"
                     displayName="ASABE Droplet Size">
                  <qualifier xsi:type="CR">
                     <value code="{ASABE Droplet Size Code}"
                            codeSystem="2.16.840.1.113883.6.275.1"
                            displayName="{ASABE Droplet Size
DisplayName}"/>
                  </qualifier>
                  </code>
               </requirement>
            </component>
```

5.2.3.3.18   *Soil Incorporation Depth and Time*

Identifies the minimum soil incorporation depth that is required for the application, and the maximum amount of time that may pass before incorporation takes place. If the incorporation is done during application, enter the time as "0" minutes.

Entry type: value unit, value unit.

Validation Procedures:

5.2.3.3.18.1 There is zero to one Soil Incorporation Depth and Time observations.

5.2.3.3.18.2 The sequenceNumber value is 3.

5.2.3.3.18.3 The Maximum time after application is a number.

5.2.3.3.18.4 The Maximum time unit is a time unit.

5.2.3.3.18.5 The Minimum depth is a number.

5.2.3.3.18.6 The Minimum depth unit is a Standard Length units.

5.2.3.3.18.7 If Soil Incorporation Depth and Time is provided at the Site or Scenario Level, then it should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Soil Incorporation Min Depth -->
            <component>
               <!-- after application -->
               <sequenceNumber value="3"/>

               <!-- wait some period of time -->
               <pauseQuantity xsi:type="PQ" nullFlavor="OTH">
                 <translation value="{Maximum time after application}"
                       displayName="{Unit DisplayName}"
                       code="{Unit Code}"
                       codeSystem="2.16.840.1.113883.6.275.1"/>
               </pauseQuantity>

               <!-- conduct observation -->
               <monitoringObservation>
                  <code code="1005331"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Soil Incorporation Depth and Time"/>

                  <precondition>
                     <observationCriterion>
                        <!-- Soil Incorporation Min Depth -->
                        <code code="1005332"
                              codeSystem="2.16.840.1.113883.6.275.1"
                              displayName="Soil Incorporation Min
Depth"/>

                        <value xsi:type="IVL_PQ">
                          <low xsi:type="IVXB_PQ" nullFlavor="OTH">
                            <translation code="{Unit Code}"
                                  codeSystem="2.16.840.1.113883.6.275.1"
                                  displayName="{Unit DisplayName"
```

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```
                                          value="{Minimum Depth}"/>
                        </low>
                      </value>
                  </observationCriterion>
                </precondition>
            </monitoringObservation>
          </component>
```

5.2.3.3.19   *Restricted Soil Type* (+)

Identifies any soil type(s) to which the product cannot be applied using these methods.

Entry type: "*Soil Type*" picklist selection, and value unit.

Validation Procedures:

5.2.3.3.19.1 There is zero to many Restricted Soil Type preconditions.
5.2.3.3.19.2 The checkPoint code is 'B'.
5.2.3.3.19.3 Code is from the list *Soil Type*.
5.2.3.3.19.4 DisplayName matches the code.
5.2.3.3.19.5 If Restricted Soil Type is provided at the Site or Scenario Level, then
              it should not also be provided at the Product level.

Xml Code Snippet:

```xml
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
        <protocol>

           <!-- other elements -->

          <!-- (0..*) Restricted Soil Type -->
          <precondition>
            <!-- observation checked before application -->
            <checkpointCode code="B"/>

            <observationCriterion>

               <code code="1004961"
                     codeSystem="2.16.840.1.113883.6.275.1"
                     displayName="Soil Type"/>

               <value xsi:type="CD" code="{Restricted Soil Type}"
                     codeSystem="2.16.840.1.113883.6.275.1"
                     displayName="{Restricted Soil Type DisplayName}"
/>

               <!-- not the condition -->
               <valueNegationInd value="true"/>

            </observationCriterion>
          </precondition>
```

5.2.3.3.20   *Minimum Percent Soil Organic Matter*

Identifies the minimum percent soil organic matter to which application(s) may be made.

Entry type: value unit.

Validation Procedures:

5.2.3.3.20.1 There is zero to one Minimum Percent Soil Organic Matter precondition.
5.2.3.3.20.2 The checkPoint code is 'B'.
5.2.3.3.20.3 The Percent Soil value is a number.
5.2.3.3.20.4 The units are Percent (code "3627136") with displayName "%".
5.2.3.3.20.5 If Minimum Percent Soil Organic Matter Precondition is provided at the Site or Scenario Level, then it should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

             <!-- other elements -->

            <!-- (0..1) Minimum Percent Soil Organic Matter -->
            <precondition>

               <!-- observation checked before application -->
               <checkpointCode code="B"/>

               <observationCriterion>

                  <code code="1005333"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Percent Soil Organic Matter"/>

                  <value xsi:type="PQ" nullFlavor="OTH">
                    <translation code="3627136"
                          codeSystem="2.16.840.1.113883.6.275.1"
                          displayName="%"
                          value="{Percent Soil Organic Matter}"/>
                  </value>

               </observationCriterion>
            </precondition>
```

5.2.3.3.21   *Minimum Age of Animal to be treated*

Identifies the minimum age of animals to which application(s) may be made.

Entry type: value unit.

Validation Procedures:

5.2.3.3.21.1 There is zero to one Minimum Age preconditions.

5.2.3.3.21.2 The checkPoint code is 'B'.

5.2.3.3.21.3 The Minimum Age is a number.

5.2.3.3.21.4 Minimum Age units must be time units.

5.2.3.3.21.5 If Minimum Age preconditions is provided at the Site or Scenario
Level, then it should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Minimum Age of Animal to be treated -->
            <precondition>
               <!-- observation checked before application -->
               <checkpointCode code="B"/>

               <observationCriterion>
                 <code code="1005334"
                       codeSystem="2.16.840.1.113883.6.275.1"
                       displayName="Minimum Age of Animal to be
treated"/>
                  <value xsi:type="PQ" nullFlavor="OTH">
                    <translation value="{Minimum Age}"
                              displayName="{Units DisplayName}"
                              code="{Minimum Age units}"
                              codeSystem="2.16.840.1.113883.6.275.1"/>
                  </value>
                </observationCriterion>
             </precondition>
```

5.2.3.3.22   Minimum Weight of Animal to be treated

Identifies the minimum weight of animals to which application(s) may be made.

Entry type: value unit.

Validation Procedures:

5.2.3.3.22.1 There is zero to one Minimum Weight preconditions.

5.2.3.3.22.2 The checkPoint code is 'B'.

5.2.3.3.22.3 The Minimum Weight is a number.

5.2.3.3.22.4 The Minimum Weight units must be Standard Weight/Capacity
units.

5.2.3.3.22.5 If Minimum Weight is provided at the Site or Scenario Level, then it
should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
```

```
              <protocol>

                 <!-- other elements -->

                 <!-- (0..1) Minimum Weight of Animal to be treated -->
                 <precondition>
                    <!-- observation checked before application -->
                    <checkpointCode code="B"/>

                    <observationCriterion>
                       <code code="1005335 "
codeSystem="2.16.840.1.113883.6.275.1"
                                  displayName="Minimum Weight of Animal"/>

                       <value xsi:type="PQ" nullFlavor="OTH">
                         <translation value="{Minimum Weight}"
                                  displayName="{Units DisplayName}"
                                  code="{Minimum Age units}"
                                  codeSystem="2.16.840.1.113883.6.275.1"/>
                       </value>
                    </observationCriterion>
                 </precondition>
```

5.2.3.3.23   Pollinator (+)

Identifies specific label restrictions to application based on pollinator protection. The statements selected from the picklist and those that appear on the label may not be identical, but must have the same general meaning.

Entry type: "*Pollinator Protection Statements*" picklist selection.

Validation Procedures:

5.2.3.3.23.1 There is zero to many Pollinator Protection Statement requirements.
5.2.3.3.23.2 Code is from the list *Pollinator Protection Statements*.
5.2.3.3.23.3 DisplayName matches the code.
5.2.3.3.23.4 If Pollinator is provided at the Site or Scenario Level, then it should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Pollinator -->
            <component>
               <requirement>
                  <code code="1005022"
codeSystem="2.16.840.1.113883.6.275.1"
                           displayName="Pollinator Protect Statements">
                     <qualifier xsi:type="CR">
                        <value code="{Pollinator Code}"
```

```
                                        codeSystem="2.16.840.1.113883.6.275.1"
                                        displayName="{Pollinator DisplayName}"/>
                        </qualifier>
                    </code>
                </requirement>
            </component>
```

5.2.3.3.24   *Bulletins Live*

Identifies if there is an Endangered Species County Level Bulletin indicator on the label. This is a presence/absence indicator. If a Bulletins Live statement appears on the label, then Bulletins Live should be selected.

Entry type: presence/absence selection.

Validation Procedures:

5.2.3.3.24.1 There is zero to one Bulletins Live requirements.

5.2.3.3.24.2 If Bulletins Live is provided at the Site or Scenario Level, then it should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Bulletins Live -->
            <component>
               <requirement>
                  <code code="1005336"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Bulletins Live"/>
               </requirement>
            </component>
```

5.2.3.3.25   *Applications to Water* (+)

Identifies specific label restrictions related to the treatment of a volume of water (includes flooded field applications and waterbodies). The statements selected from the picklist and those that appear on the label may not be identical, but must have the same general meaning.

Entry type: "*Water Protection Statements*" picklist selection.

Validation Procedures:

5.2.3.3.25.1 There is zero to many Applications to Water requirements.

5.2.3.3.25.2 Code is from the list *Water Protection Statements*.

5.2.3.3.25.3 DisplayName matches the code.

5.2.3.3.25.4 If Applications to Water is provided at the Site or Scenario Level,
then it should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Applications to Water -->
            <component>
                     <requirement>
                  <code code="1005023"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Water Protection Statement">
                     <qualifier xsi:type="CR">
                        <value code="{Water Protection Statement Code}"
                                 codeSystem="2.16.840.1.113883.6.275.1"
                                 displayName="{Water Protection Statement
DisplayName}"/>
                     </qualifier>
                  </code>
               </requirement>
            </component>
```

5.2.3.3.26   *Secondary Manufacturing*

Identifies if there are any restrictions which limit further manufacturing of the treated
material (e.g., restricting treated plastics in the manufacture of toys). This is a
presence/absence indicator. If any restrictions limiting secondary manufacture appear on
the label, then Secondary Manufacture should be selected.

Entry type: presence/absence selection.

Validation Procedures:

5.2.3.3.26.1 There is zero to one Secondary Manufacturing requirements.
5.2.3.3.26.2 If Secondary Manufacturing is provided at the Site or Scenario
Level, then it should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- Secondary Manufacturing -->
            <component>
```

```
                    <requirement>
                        <code code="1005337"
codeSystem="2.16.840.1.113883.6.275.1"
                            displayName="Secondary Manufacturing"/>
                    </requirement>
                </component>
```

5.2.3.3.27   *Restricted Use Site Location* (+)

Identifies if applications are not permitted in specific Use Site Locations. Locations entered as restricted cannot be entered as permitted in the site attribute sections at lower levels of the model. Generally, elements that are not positively entered in the attributes section of this document are considered to be disallowed. This restriction should only be entered if the text of the label explicitly prohibits use in a particular use site location.

Entry type: "*Use Site Location*" picklist selection.

Validation Procedures:

5.2.3.3.27.1 There is zero to many Restricted Use Location preconditions.
5.2.3.3.27.2 The checkpointCode code is 'B'.
5.2.3.3.27.3 Code is from the list *Use Site Location*.
5.2.3.3.27.4 DisplayName matches the code.
5.2.3.3.27.5 If Restricted Use Location is provided at the Site or Scenario Level, then it should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
    <substanceAdministration>
        <componentOf>
            <protocol>

            <!-- other elements -->

            <!-- (0..*) Restricted Locations -->
            <precondition>
                <!-- observation checked before application -->
                <checkpointCode code="B"/>

                <observationCriterion>
                    <code code="1004663"
codeSystem="2.16.840.1.113883.6.275.1"
                            displayName="Use Site Location"/>

                    <value xsi:type="CD" code="{Use Site Location Code}"

        codeSystem="2.16.840.1.113883.6.275.1"
                            displayName="{Use Site Location DisplayName}"/>

                    <!-- not the condition -->
                    <valueNegationInd value="true"/>
                </observationCriterion>
            </precondition>
```

5.2.3.3.28   *Restricted Application Target* (+)

Identifies if applications are not permitted to specific targets. Targets entered as restricted cannot be entered as permitted in scenario attribute sections at lower levels of the model. Generally, elements that are not positively entered in the attributes section of this document are considered to be disallowed. This restriction should only be entered if the text of the label explicitly prohibits this type of application.

Entry type: "*Application Target*" picklist selection.

Validation Procedures:

5.2.3.3.28.1 There is zero to many Restricted Application Target preconditions.
5.2.3.3.28.2 The checkpointCode code is 'B'.
5.2.3.3.28.3 Code is from the list *Application Target*.
5.2.3.3.28.4 DisplayName matches the code.
5.2.3.3.28.5 If Restricted Application Target is provided at the Site or Scenario Level, then it should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Restricted Application Target -->
            <precondition>
               <!-- observation checked before application -->
               <checkpointCode code="B"/>

               <observationCriterion>

                  <code code="1004682"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Application Target"/>

                  <value xsi:type="CD" code="{Application Target Code}"

      codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="{Application Target DisplayName}"/>

                  <!-- not the condition -->
                  <valueNegationInd value="true"/>
               </observationCriterion>
            </precondition>
```

5.2.3.3.29   *Restricted Application Type* (+)

Identifies if applications are not permitted using specific application types. Application types entered as restricted cannot be entered as permitted in scenario attribute sections at lower levels of the model. Generally, elements that are not positively entered in the

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attributes section of this document are considered to be disallowed. This restriction should only be entered if the text of the label explicitly prohibits this type of application.

Entry type: "*Application Type*" picklist selection.

Validation Procedures:
5.2.3.3.29.1 There is zero to many Restricted Application Type preconditions.
5.2.3.3.29.2 The checkpointCode code is 'B'.
5.2.3.3.29.3 Code is from the list *Application Type*.
5.2.3.3.29.4 DisplayName matches the code.
5.2.3.3.29.5 If Restricted Application Type is provided at the Site or Scenario Level, then it should not also be provided at the Product level.

Xml Code Snippet:

```xml
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Restricted Application Type -->
            <precondition>
               <!-- observation checked before application -->
               <checkpointCode code="B"/>

               <observationCriterion>

                  <code code="1004920"
codeSystem="2.16.840.1.113883.6.275.1"
                     displayName="Application Type"/>

                  <value xsi:type="CD" code="{Application Type Code}"

      codeSystem="2.16.840.1.113883.6.275.1"
                     displayName="{Application Type DisplayName}"/>

                  <!-- not the condition -->
                  <valueNegationInd value="true"/>
               </observationCriterion>
            </precondition>
```

5.2.3.3.30   *Restricted Application Equipment* (+)

Identifies if applications are not permitted using specific equipment. Equipment entered as restricted cannot be entered as permitted in scenario attribute sections at lower levels of the model. Generally, elements that are not positively entered in the attributes section of this document are considered to be disallowed. This restriction should only be entered if the text of the label explicitly prohibits this type of application.

Entry type: "*Application Equipment*" picklist selection.

Validation Procedures:

5.2.3.3.30.1 There is zero to many Restricted Application Equipment preconditions.

5.2.3.3.30.2 The checkpointCode code is 'B'.

5.2.3.3.30.3 Code is from the list *Application Equipment*.

5.2.3.3.30.4 DisplayName matches the code.

5.2.3.3.30.5 If Restricted Application Equipment is provided at the Site or Scenario Level, then it should not also be provided at the Product level.

Xml Code Snippet:

```xml
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Restricted Application Equipment -->
            <precondition>
               <!-- observation checked before application -->
               <checkpointCode code="B"/>

               <observationCriterion>
                  <code code="1004922"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Application Equipment"/>

                  <value xsi:type="CD" code="{Application Equipment
Code}"

      codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="{Application Equipment
DisplayName}"/>

                  <!-- not the condition -->
                  <valueNegationInd value="true"/>
               </observationCriterion>
            </precondition>
```

5.2.3.3.31   *Restricted Application Timing* (+)

Identifies if applications are not permitted during specific timings. Timings entered as restricted cannot be entered as permitted in scenario attribute sections at lower levels of the model. Generally, elements that are not positively entered in the attributes section of this document are considered to be disallowed. This restriction should only be entered if the text of the label explicitly prohibits this type of application.

Entry type: "*Application Timing (Time of Day)"," Application Timing (Timing of Pest)", and/or "Application Timing (Use Site Status)*" picklist selection.

Validation Procedures:

5.2.3.3.31.1 There is zero to many Restricted Application Timing (Time of Day), Restricted Application Time (Timing of Pest) or Application Timing (Use Site Status) preconditions.

5.2.3.3.31.2 The checkpointCode code is 'B'.

5.2.3.3.31.3 The Application Timing Code is defined in the appropriate *Application Timing (Time of Day), Application Timing (Timing of Pest) or Application Timing (Use Site Status)* list

5.2.3.3.31.4 DisplayName matches the code.

5.2.3.3.31.5 If Restricted Application Timing is provided at the Site or Scenario Level, then it should not also be provided at the Product level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
        <protocol>

            <!-- other elements -->

            <!-- (0..*) Restricted App Timing (Time of Day) -->
            <precondition>
               <!-- observation checked before application -->
               <checkpointCode code="B"/>

               <observationCriterion>
                  <code code="1004921"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Application Timing (Time of Day)"/>

                  <value xsi:type="CD" code="{Application Timing Code}"
       codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="{Application Timing DisplayName}"/>

                  <!-- not the condition -->
                  <valueNegationInd value="true"/>
               </observationCriterion>
            </precondition>

            <!-- (0..*) Restricted App Timing -->
            <precondition>
               <!-- observation checked before application -->
               <checkpointCode code="B"/>

               <observationCriterion>
                  <code code="1005020"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Application Timing (Timing of
Pest)"/>

                  <value xsi:type="CD" code="{Application Timing Code}"
       codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="{Application Timing DisplayName}"/>

                  <!-- not the condition -->
```

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```
                    <valueNegationInd value="true"/>
                </observationCriterion>
            </precondition>

            <!-- (0..*) Restricted App Timing -->
            <precondition>
                <!-- observation checked before application -->
                <checkpointCode code="B"/>

                <observationCriterion>
                    <code code="1004960"
codeSystem="2.16.840.1.113883.6.275.1"
                            displayName="{Application Timing (Use Site
Status)}"/>

                    <value xsi:type="CD" code="{Application Timing Code}"

        codeSystem="2.16.840.1.113883.6.275.1"
                            displayName="{Application Timing DisplayName}"/>

                    <!-- not the condition -->
                    <valueNegationInd value="true"/>
                </observationCriterion>
            </precondition>
```

5.2.4 Site Level (+)

The "Site Level" section is a header section to contain the subsections defined herein, and "Scenario Level" subsections. The "Site Level" section can be cloned/repeated to create many Site level sections within a "Product Level" section.

Each Site is defined as a place with the combination of Use Site Attributes (Use Site and Location) to which the product can be applied with the same maximum yearly or crop cycle rate (from all Scenarios combined). Changes to the overall maximum yearly rate allowed for a Site trigger the creation of a new Site, however, differences in the rate that can be applied from any one method can be recorded at the Scenario Level. Differences in restrictions associated with a particular application method can also be recorded at the Scenario Level.

The system is flexible in that if all of the Site Level rate and restriction elements are identical, then multiple Site Attributes may be listed as a single Site. Likewise, if a label has more complicated application instructions, then additional Sites can be added to isolate caveats to the maximum use. This may also include use of the "Geographic Restriction" when rates differ based on geography. Before entering information to define a Site, look across the application instructions for the Product to determine if there are unique use pattern parameters. For example, if there are different maximum yearly application rates associated with applications to turf in residential and agricultural settings, then a separate site is entered for each. Similarly, if the parameters do not change with variations in Use Site, Use Site Location, or Restrictions/Limitations, then a single Site can capture all the details by simply selecting multiple values from the picklists. It is important to remember, however, that all combination of these selections must be allowable.

Each Site must have at least one Scenario. The "Site Level" section can be repeated to create many Use Site Sections. For example:

- Site Level 1
    - o Use Site Attributes
        - ▪ Use Site 1
        - ▪ Use Site Location 1
        - ▪ Use Site Location 2

- Site Level 2
    - o Use Site Attributes
        - ▪ Use Site 2
        - ▪ Use Site Location 1
        - ▪ Use Site Location 2

Information entered in the Use Site Level subsections applies to all Scenarios of the Use Site.

Validation Procedures:

5.2.4.1.1.1   There is at least one "Site Level" section per document.
5.2.4.1.1.2   The section title is the same as the section code displayName.
5.2.4.1.1.3   The section link is optional.
5.2.4.1.1.4   If the section link is provided then the section link is a unique string within the document.
5.2.4.1.1.5   The section id is a unique UUID within the document.

Xml Code Snippet:

```
<component>
   <section ID="{Section Link}">
      <id root="{Section Id}"/>
      <code code="3810087" codeSystem="2.16.840.1.113883.6.275.1"
            displayName="Site Level"/>
      <title>Site Level</title>
```

5.2.4.2   Use Site Attributes

The "Use Site Attributes" section is a subsection of the "Site Level" section. The site attributes listed below describe in detail to what and where a product can be applied. Multiple site attributes can be entered if ALL subsequent application information applies to all combinations of the attributes. The "Use Site Attributes" section captures the following data elements:

- **Use Site**
    - o Identifies the use site. For crop use sites, the list includes all crops and crop groups. For non-crop use sites the list is comprised of higher level categories. See the use site guidance document and "Use Site/Commodity" for guidance.

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<div align="center"><u>**Entry type:**</u> "*Use Site/Commodity*" picklist selection.</div>

- **Use Site Location (+)**
  - o Location of pesticide activity gives a broad category-based description of where the pesticide treatment is taking place (e.g. Agricultural (indoor), Agricultural (outdoor), Medical/Hospital/Veterinary Facility (Indoor), etc). The Use Site and Use Site Location work together to fully define where pesticide application occurs.

<div align="center"><u>**Entry type:**</u> "*Use Site Location*" picklist selection.</div>

Validation Procedures:

5.2.4.2.1.1	There is one "Use Site Attributes" section per "Site Level" section.
5.2.4.2.1.2	The section title is the same as the section code displayName.
5.2.4.2.1.3	The section link is optional.
5.2.4.2.1.4	If the section link is provided then the section link is a unique string within the document.
5.2.4.2.1.5	The section id is a unique UUID within the document.
5.2.4.2.1.6	There is one Use Site code and name.
5.2.4.2.1.7	Use Site code is from the list *Use Site/Commodity*.
5.2.4.2.1.8	The Use Site Code displayName matches the code.
5.2.4.2.1.9	There is at least one Use Site Location code and name.
5.2.4.2.1.10	Use Site Location code cannot be a code restricted in Product Level section.
5.2.4.2.1.11	The Use Site Location Code is from the list *Use Site Location*.
5.2.4.2.1.12	The Use Site Location Code displayName matches the code.

Xml Code Snippet:

```
<component>
   <section ID="{Section Link}">
      <id root="{Section Id}"/>
      <code code="3810088" codeSystem="2.16.840.1.113883.6.275.1"
            displayName="Use Site Attributes"/>
      <title>Use Site Attributes</title>

      <subject2>
         <substanceAdministration>
            <subject>
               <presentSubstance classCode="LOCE">

                  <approachSiteCode code="{Use Site Location Code}"
                        codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="{DisplayName}"/>

                  <!-- Additional Use Site Locations -->
                  <approachSiteCode code="{Use Site Location Code}"
                        codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="{DisplayName}"/>
```

```
            <presentSubstance classCode="LOCE">
              <presentSubstance>
                <code code="{Use Site Code}"
                      codeSystem="2.16.840.1.113883.6.275.1"
                      displayName="{DisplayName}"/>
                <name>{Use Site DisplayName}</name>
              </presentSubstance>
            </presentSubstance>
          </subject>
        </substanceAdministration>
      </subject2>
    </section>
</component>
```

5.2.4.3   Use Site Yearly/Crop Cycle Rate

The "Use Site Yearly Rate" section captures at least one of the following elements:

- **Maximum Number of Applications per Site per Year or per Crop Cycle.**
    - Identifies the maximum number of applications that can be applied per year or crop cycle to the use site from all scenarios combined.

        Entry type: value per "*Application Rate Measurement Period"* picklist selection.

- **Maximum Site Application Rate per Year or per Crop Cycle.**
    - Identifies the maximum amount of product that can be applied per year or crop cycle to the use site from all scenarios combined.

        Entry type: value unit per value unit, per "*Application Rate Measurement Period"* picklist selection.

If both the maximum number of applications and the maximum rate are given, enter information as either per year or per crop cycle, not both.
If the site maximum number of applications or the maximum application rate are expressed in terms of per crop cycle, the maximum number of crop cycles per year must be recorded using the "Maximum Number of Crop Cycles per Year" field at the Scenario Levels.

Validation Procedures:

5.2.4.3.1.1   There is one "Use Site Yearly Rate" section per "Site Level" section.
5.2.4.3.1.2   The section title is the same as the section code displayName.
5.2.4.3.1.3   The section link is optional.
5.2.4.3.1.4   If the section link is provided then the section link is a unique string within the document.
5.2.4.3.1.5   The section id is a unique UUID within the document.
5.2.4.3.1.6   There is at least one characteristic, either Maximum Number of Applications, Maximum Application Rate or both.

5.2.4.3.1.7   The Maximum Application Rate numerator and denominator value
     are numbers.

5.2.4.3.1.8   Maximum Application Rate numerator units must be one of the
     following:

- Standard Weight / Mass
- Standard Volume / Capacity
- Miscellaneous Application Unit
- Concentration
- Non-Standard Volume / Capacity

5.2.4.3.1.9   Maximum Application Rate denominator units must be one of the
     following:

- Standard Area
- Standard Length
- Standard Weight / Mass
- Standard Volume / Capacity
- Time
- Blank (if numerator is Concentration)
- Non-Standard Volume / Capacity
- Non-standard - Target (with acreage rate limit)
- Non-Standard Weight / Mass
- Miscellaneous – Target

5.2.4.3.1.10   The Maximum Number of Applications value is a number.

5.2.4.3.1.11   The Maximum Number of Applications value cannot exceed the
     value in the "Product Level Use Restrictions/Limitations".

5.2.4.3.1.12   Method code is from the list *Application Rate Measurement Period*.

Xml Code Snippet:

```
<component>
   <section ID="{Section Link}">
      <id root="{Section Id}"/>
      <code code="3810089" codeSystem="2.16.840.1.113883.6.275.1"
            displayName="Use Site Yearly Rate"/>
      <title>Use Site Yearly Rate</title>
      <subject2>
         <substanceAdministration>

            <componentOf>
               <protocol>
                  <component>
                     <substanceAdministration>

                        <!-- Maximum Application Rate per Time -->
                        <subjectOf>
                           <characteristic>
                              <code code="1005313"
                                 codeSystem="2.16.840.1.113883.6.275.1"
                                 displayName="Maximum Application Rate"/>
                              <value xsi:type="RTO_PQ_PQ">
                                 <numerator xsi:type="PQ" nullFlavor="OTH">
```

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```
                                        <translation value="{Maximum Rate}"
                                           displayName="{Unit DisplayName}"
                                           code="3627132"

codeSystem="2.16.840.1.113883.6.275.1"/>
                                        </numerator>
                                        <denominator xsi:type="PQ"
nullFlavor="OTH">

                                           <translation value="{Per Quantity}"
                                              displayName="{Unit DisplayName}"
                                              code="{Unit Code}"

codeSystem="2.16.840.1.113883.6.275.1"/>
                                        </denominator>
                                     </value>
                                     <methodCode code="{Method Code}"
                                           codeSystem="2.16.840.1.113883.6.275.1"
                                           displayName="{DisplayName}"/>
                                  </characteristic>
                               </subjectOf>

                               <!-- Maximum Number of Applications per Site -->
                               <subjectOf>
                                  <characteristic>
                                     <code code="1005312"
                                           codeSystem="2.16.840.1.113883.6.275.1"
                                           displayName="Maximum Applications per
Site"/>
                                     <value xsi:type="PQ"
                                           value="{Maximum Number}"
                                           unit="1"/>
                                     <methodCode code="{Method Code}"
                                           codeSystem="2.16.840.1.113883.6.275.1"
                                           displayName="{DisplayName}"/>
                                  </characteristic>
                               </subjectOf>
                            </substanceAdministration>
                         </component>
                     </protocol>
                  </componentOf>

            </substanceAdministration>
         </subject2>
      </section>
</component>
```

5.2.4.4   Use Site Level Restrictions/Limitations

Identifies only Use Site Level Restrictions/Limitations, which are applicable to all of the
Use Site's Scenario Levels. If a restriction/limitation differs between scenarios, it should
be entered only at the scenario level. Information for the same Restriction/Limitation
cannot be entered at multiple levels. Restrictions/Limitations should only be recorded in
the Use Index if the label explicitly restricts or limits the identified data element in
legally enforceable language. Statements that include terms like "should" or "for best
results" are not legally enforceable, and should not be recorded.

Multiple entries are possible for many Restrictions/Limitations. In this document, data
elements that may have multiple entries are marked with a (+) after their title.

Additoinally, the validation rules for each element indicate if entry is optional and the number of entries that can be entered.

Leaving a restriction blank indicates that there is no restriction at this level.

Validation Procedures:

5.2.4.4.1.1 There is one "Use Site Level Restrictions/Limitations" section per "Site Level" section.
5.2.4.4.1.2 The section title is the same as the section code displayName.
5.2.4.4.1.3 The section link is optional.
5.2.4.4.1.4 If the section link is provided then the section link is a unique string within the document.
5.2.4.4.1.5 The section id is a unique UUID within the document.

Xml Code Snippet:

```
<component>
   <section ID="{Section Link}">
      <id root="{Section Id}"/>
      <code code="3810090" codeSystem="2.16.840.1.113883.6.275.1"
            displayName="Use Site Level Restrictions/Limitations"/>
      <title>Use Site Level Restrictions/Limitations</title>
```

5.2.4.4.2 Geographic Area Allowed (+)

Identifies restrictions associated with geographic location, at the state and county level, by listing areas where application *is* allowed. This is a required field at either the Product, Site, or Scenario level for each method. If applications are not restricted to any particular geographic area, select "United States". If application is not allowed in a particular area, select all areas except the prohibited area.

Entry type: "*Geographic Area*" picklist selection.

Validation Procedures:

5.2.4.4.2.1 There is at least one Geographic Area for each scenario. The scenario is considered to have Geographic Area if it is provided at the Product, Site, or Scenario levels.
5.2.4.4.2.2 If Geographic Area is provided at the Product or Scenario level (all Scenario Levels within a Site), there should be no Geographic Area provided at the Site level.
5.2.4.4.2.3 Code is from the list "*Geographic Area*".
5.2.4.4.2.4 DisplayName matches the code.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
```

```
            <protocol>

              <!-- other elements -->

              <!-- (1..*) Geographic Area Allowed -->
              <component>
                 <requirement>
                    <code code="1005202"
codeSystem="2.16.840.1.113883.6.275.1"
                          displayName="Geographic Area">
                       <qualifier xsi:type="CR">
                          <value code="{Geographic Area Code}"
                                 codeSystem="2.16.840.1.113883.6.275.1"
                                 displayName="{Geographic Area
DisplayName}"/>
                       </qualifier>
                    </code>
                 </requirement>
              </component>
```

5.2.4.4.3 Food Site Relationship

Identifies if application(s) are intended to come in contact with food or feed, which may result in the need for a tolerance. This information is required for agricultural crops (at either the Product, Site, or Scenario level for each method) to establish whether crops may be used as food or feed (Bearing), or may not be used as food or feed (Non-Bearing/Dormant, Grown for Seed) If the product labeling for non-agricultural sites explicitly prohibits applications that may contact food or feed, No Food/Feed Contact should be selected (see definitions for further guidance).

Entry type: "*Use Site Food Relationship*" picklist selection.

Validation Procedures:

5.2.4.4.3.1   There is one Food Site Relationship for each scenario. The Scenario is considered to have a Food Site Relationship if it is provided at the Product, Site, or Scenario Levels.

5.2.4.4.3.2   If Food Site Relationship is provided at the Product or Scenario levels (Scenarios under a site), there should be no Food Site Relationship provided at the Site level.

5.2.4.4.3.3   Code is from the list *Use Site Food Relationship*.

5.2.4.4.3.4   DisplayName matches the code.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

           <!-- other elements -->

           <!-- (1..1) Food Site Relationship -->
           <component>
              <requirement>
                 <code code="1005021"
```

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```
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Use Site Food Relationship">
                    <qualifier xsi:type="CR">
                        <value code="{Use Site Food Relationship Code}"
                                codeSystem="2.16.840.1.113883.6.275.1"
                                displayName="{Use Site Food Relationship
DisplayName}"/>
                    </qualifier>
                </code>
            </requirement>
        </component>
```

5.2.4.4.4 Restriction Maximum Active Ingredient Rate Across Products

Identifies the maximum amount of active ingredient (or in some cases the maximum amount of a chemical class) that may be applied to a given area across products that contain the same active ingredient (or a.i. class). This restriction is often stated on labels as "Do not apply more than [x amount] of product per [year or crop cycle] from this or any other product containing this active ingredient".

> **Entry type:** value unit, per value unit, per "*Application Rate Measurement Period"* picklist selection.

Validation Procedures:

5.2.4.4.4.1　There are zero or one Restriction Maximum Active Ingredient Rate Across Products substanceAdministrations.

5.2.4.4.4.2　If Maximum Active Ingredient Rate Across Products substanceAdministrations is provided at the Product or Scenario Level, then there should not also be a Maximum Active Ingredient Rate Across Products substance Administrations provided at the Site level.

5.2.4.4.4.3　The Maximum Rate is a number.

5.2.4.4.4.4　Numerator units must be one of the following:

- Standard Weight / Mass
- Standard Volume / Capacity
- Miscellaneous Application Unit
- Concentration
- Non-Standard Volume / Capacity

5.2.4.4.4.5　Denominator units must be one of the following:

- Standard Area
- Standard Length
- Standard Weight / Mass
- Standard Volume / Capacity
- Time
- Blank (if numerator is Concentration)
- Non-Standard Volume / Capacity
- Non-standard - Target (with acreage rate limit)

- Non-Standard Weight / Mass
- Miscellaneous – Target

5.2.4.4.4.6   Method code is from the list *Application Rate Measurement Period*.

<u>Xml Code Snippet:</u>

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
    <substanceAdministration>
        <componentOf>
            <protocol>

            <!-- other elements -->

            <!-- (0..1) Restriction Max A.I. Rate Across Products -->
            <component>
              <substanceAdministration>
                <subjectOf>
                  <characteristic>
                    <code code="1005323"
                          codeSystem="2.16.840.1.113883.6.275.1"
                          displayName="Max A.I. Rate Across Products"/>
                    <value xsi:type="RTO_PQ_PQ">
                      <numerator xsi:type="PQ" nullFlavor="OTH">
                        <translation value="{Maximum Rate}"
                              displayName="{Unit DisplayName"
                              code="{Unit Code}"
                              codeSystem="2.16.840.1.113883.6.275.1"/>
                      </numerator>
                      <denominator xsi:type="PQ" nullFlavor="OTH">
                        <translation value="{Per Quantity}"
                              displayName="{Unit DisplayName"
                              code="{Unit Code}"
                              codeSystem="2.16.840.1.113883.6.275.1"/>
                      </denominator>
                    </value>
                    <methodCode code="{Method Code}"
                          codeSystem="2.16.840.1.113883.6.275.1"
                          displayName="{Method DisplayName}"/>
                  </characteristic>
                </subjectOf>
              </substanceAdministration>
            </component>
```

5.2.4.4.5 Rotational Crop

Identifies if any rotational crop restrictions apply to this specific product. This is a presence/absence indicator. If any restrictions to rotation plantings appear on the label (including what may be planted following the current crop, or the length of time that must pass before a crop can be planted in the area), then Rotational Crop should be selected.

<u>Entry type:</u> presence/absence selection (absence selected as default).

Validation Procedures:

5.2.4.4.5.1   There is zero to one Rotational Crop requirements.
5.2.4.4.5.2   If Rotational Crop is provided at the Product or Scenario Level, then there should not also be Rotational Crop provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Rotational Crop -->
            <component>
               <requirement>
                  <code code="1005337"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Rotational Crop"/>
               </requirement>
            </component>
```

5.2.4.4.6 *Applicator Class Restrictions* (+)

Identifies those individuals or groups of individuals who are allowed to apply the product, if only certain classes of applicator are allowed. The existence of an Application Class requirement(s), by definition, indicates all other applicators are restricted from using the product.

Entry type: "*Applicator Class Restrictions*" picklist selection.

Validation Procedures:

5.2.4.4.6.1   Code is from the list *Applicator Class Restrictions*.
5.2.4.4.6.2   DisplayName matches the code.
5.2.4.4.6.3   There is zero to many Applicator Class Restrictions.
5.2.4.4.6.4   If Applicator Class Restriction(s) is/are provided at the Product or Scenario Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Applicator Class Restrictions -->
            <component>
               <requirement>
                  <code code="1004442"
```

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```
codeSystem="2.16.840.1.113883.6.275.1"
                          displayName="Applicator Class Restrictions">
                    <qualifier xsi:type="CR">
                       <value code="{Applicator Class Restriction}"
                              codeSystem="2.16.840.1.113883.6.275.1"
                              displayName="{Applicator Class
Restriction DisplayName}"/>
                    </qualifier>
                 </code>
             </requirement>
         </component>
```

5.2.4.4.7 *Personal Protection Equipment (PPE) / Engineering Control* (+)

This indicates the PPE and/or engineering controls are required on for use of the product. Information captured here is not limited to information in the Agricultural Use box on the label. It is intended to capture requirements for PPE/Engineering Controls that appear anywhere on the label.

Entry type: "*Personal Protection Equipment (PPE)/Engineering Control*" picklist selection.

Validation Procedures:

5.2.4.4.7.1   There is zero to many PPE/Engineering Control requirements.
5.2.4.4.7.2   If Personal Protection Equipment / Engineering control is/are provided at the Product or Scenario Level, then it should not also be provided at the Site level.
5.2.4.4.7.3   Code is from the list *Personal Protection Equipment (PPE)/Engineering Control*.
5.2.4.4.7.4   DisplayName matches the code.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) PPE/Engineering control -->
            <component>
               <requirement>
                  <code code="1005024"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="PPE/Engineering Control">
                     <qualifier xsi:type="CR">
                        <value code="{PPE/Engineering Control Code}"
                               codeSystem="2.16.840.1.113883.6.275.1"
                               displayName="{PPE/Engineering Control
DisplayName}"/>
                     </qualifier>
                  </code>
               </requirement>
            </component>
```

5.2.4.4.8 Restricted Entry Interval (REI)

Identifies the minimum period of time after a pesticide application when entry into the treated area is restricted. Includes WPS and non-WPS re-entry intervals.

Entry type: value unit

Validation Procedures:

5.2.4.4.8.1 There is zero to one Restricted Entry Interval requirements.
5.2.4.4.8.2 If Restricted Entry Interval is provided at the Product or Scenario Level, then it should not also be provided at the Site level.
5.2.4.4.8.3 The value of sequenceNumber must be 3.
5.2.4.4.8.4 The Period of Time is a number.
5.2.4.4.8.5 Units must be time units.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) REI -->
            <component>
               <!-- after application -->
               <sequenceNumber value="3"/>

               <requirement>
                  <code code="1005325"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Minimum period of time before worker
re-entry"/>
                  <effectiveTime xsi:type="IVL_TS">
                     <width xsi:type="PQ" nullFlavor="OTH">
                        <translation value="{Period of time value}"
                                displayName="{Unit DisplayName}"
                                code="{Unit Code}"
                                codeSystem="2.16.840.1.113883.6.275.1"/>
                     </width>
                  </effectiveTime>
               </requirement>
            </component>
```

5.2.4.4.9 Minimum Retreatment Interval (MRI)

Identifies the minimum period of time after an application that must pass before the product can be reapplied to the same area or target.

Entry type: value unit

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Validation Procedures:

5.2.4.4.9.1   There is zero to one Minimum Retreatment Interval requirements.
5.2.4.4.9.2   The value of sequenceNumber must be 3.
5.2.4.4.9.3   The Minimum Retreatment Interval is a number.
5.2.4.4.9.4   Units must be time units.
5.2.4.4.9.5   Required if more than one application is allowed, or if the single rate is not equal to the crop cycle/yearly rate.
5.2.4.4.9.6   If Minimum Retreatment Interval is provided at the Product or Scenario Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

          <!-- other elements -->

           <!-- (0..1) MRI -->
          <component>
             <!-- after application -->
             <sequenceNumber value="3"/>

             <requirement>
                <code code="1005326"
                     codeSystem="2.16.840.1.113883.6.275.1"
                     displayName="Minimum period of time before re-
application"/>

                <effectiveTime xsi:type="IVL_TS">
                  <width xsi:type="PQ" nullFlavor="OTH">
                    <translation value="{Minimum period of time}"
                            displayName="{Unit DisplayName}"
                            code="{Unit Code}"
                            codeSystem="2.16.840.1.113883.6.275.1"/>
                  </width>
                </effectiveTime>
             </requirement>
          </component>
```

5.2.4.4.10   *Pre-Harvest Interval (PHI)/ Pre-Feeding Interval* (+)

Identifies the minimum period of time that must pass after an application before crop/commodity. This data element may be blank if the final application is restricted to occur at or before a crop growth stage that is typically 30 days or more before harvest.

Entry type: "*Pre-Harvest Interval (PHI)/ Pre-Feeding Interval Category*" picklist selection, and value unit.

Validation Procedures:

5.2.4.4.10.1 There is zero to many Pre-Harvest Interval requirements.
5.2.4.4.10.2 The sequenceNumber value is 3.

5.2.4.4.10.3 Code is from the list *Pre-Harvest Interval (PHI)/ Pre-Feeding Interval Category*.
5.2.4.4.10.4 DisplayName matches the code.
5.2.4.4.10.5 The Pre-Harvest interval is a number.
5.2.4.4.10.6 Units must be time units.
5.2.4.4.10.7 If Minimum Pre-Harvest Interval is provided at the Product or Scenario Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) PHI -->
            <component>
               <!-- after application -->
               <sequenceNumber value="3"/>

               <requirement>
                  <code code="1005028"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="PHI Category">
                     <qualifier xsi:type="CR">
                        <value code="{PHI Category Code}"
                               codeSystem="2.16.840.1.113883.6.275.1"
                               displayName="{PHI Category
DisplayName}"/>
                     </qualifier>
                  </code>

                  <effectiveTime xsi:type="IVL_TS">
                     <width xsi:type="PQ" nullFlavor="OTH">
                       <translation value="{PHI Value}"
                                   code="{Unit Code}"
                                   codeSystem="2.16.840.1.113883.6.275.1"
                                   displayName="{Unit DisplayName}"/>
                     </width>
                  </effectiveTime>
               </requirement>

            </component>
```

5.2.4.4.11   *Pre-Grazing Interval (PGI)/Pre-Feeding Interval (PFI)* (+)

Identifies the minimum period of time that must pass after an application before an identified group of animals may graze in treated areas, or may be fed treated material.

Entry type: "*Pre-Grazing Interval (PGI) Category*" picklist selection, and value unit.

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Validation Procedures:

5.2.4.4.11.1 There is zero to many Pre-Grazing Intervals requirements.

5.2.4.4.11.2 The sequenceNumber value is 3.

5.2.4.4.11.3 Code is from the list Pre-Grazing Interval (PGI) Category/ Pre-Feeding Interval.

5.2.4.4.11.4 DisplayName matches the code.

5.2.4.4.11.5 The Pre-Grazing interval is a number.

5.2.4.4.11.6 Units must be time units.

5.2.4.4.11.7 If GPI/PFI is provided at the Product or Scenario Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) PGI -->
            <component>

               <!-- after application -->
               <sequenceNumber value="3"/>

               <requirement>
                  <code code="1005026"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="PGI Category">
                     <qualifier xsi:type="CR">
                        <value code="{PGI Category Code}"
                                 codeSystem="2.16.840.1.113883.6.275.1"
                                 displayName="{PGI Category
DisplayName}"/>
                     </qualifier>
                  </code>

                  <effectiveTime xsi:type="IVL_TS">
                    <width xsi:type="PQ" nullFlavor="OTH">
                      <translation value="{Pre-Grazing Interval}"
                                 code="{Unit Code}"
                                 codeSystem="2.16.840.1.113883.6.275.1"
                                 displayName="{Unit DisplayName}"/>
                    </width>
                  </effectiveTime>
               </requirement>
            </component>
```

5.2.4.4.12   Pre-Slaughter Interval (PSI) (+)

Identifies the minimum period of time after an application that must pass before an identified group of animals that have contacted the product can be slaughtered for food or feed.

Entry type: "*Pre-Slaughter Interval (PSI) Category*" picklist selection, and value unit.

Validation Procedures:

5.2.4.4.12.1 There is zero to many Pre-Slaughter Interval requirements.

5.2.4.4.12.2 The sequenceNumber value is 3.

5.2.4.4.12.3 Code is from the list *Pre-Slaughter Interval (PSI) Category*.

5.2.4.4.12.4 DisplayName matches the code.

5.2.4.4.12.5 Pre-Slaughter interval is a number.

5.2.4.4.12.6 If PSI is provided at the Product or Scenario Level, then it should not also be provided at the Site level.

5.2.4.4.12.7 Units must be time units.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) PSI -->
            <component>
               <!-- after application -->
               <sequenceNumber value="3"/>

               <requirement>
                  <code code="1005027"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="PSI Category">
                     <qualifier xsi:type="CR">
                        <value code="{PSI Category Code}"
                               codeSystem="2.16.840.1.113883.6.275.1"
                               displayName="{PSI Category
DisplayName}"/>
                     </qualifier>
                  </code>

                  <effectiveTime xsi:type="IVL_TS">
                    <width xsi:type="PQ" nullFlavor="OTH">
                      <translation value="{Pre-Slaughter Interval}"
                               code="{Unit Code}"
                               codeSystem="2.16.840.1.113883.6.275.1"
                               displayName="{Unit DisplayName}"/>
                    </width>
                  </effectiveTime>
               </requirement>
            </component>
```

5.2.4.4.13   *Buffer Zone* (+)

Identifies the minimum distance that is required between the area where a product is applied and the specific area to be protected from the pesticide application.

Entry type: "*Buffered Area*" picklist selection, and value unit.

Validation Procedures:

5.2.4.4.13.1 There is zero to many Buffer Area preconditions.
5.2.4.4.13.2 The checkPoint code is 'T'.
5.2.4.4.13.3 Code is from the list *Buffered Area*.
5.2.4.4.13.4 DisplayName matches the code.
5.2.4.4.13.5 The Buffered Area value is a number.
5.2.4.4.13.6 Units must be Standard Length units.
5.2.4.4.13.7 If Buffer Zone is provided at the Product or Scenario Level, then it
         should not also be provided at the Site level.

Xml Code Snippet:

```xml
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Buffer Zone -->
            <precondition>
               <!-- observation must hold true throughout application -->
               <checkpointCode code="T"/>

                <observationCriterion>
                  <code code="1004980"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Buffered Area">
                     <qualifier xsi:type="CR">
                        <value code="{Buffered Area Code}"
                               codeSystem="2.16.840.1.113883.6.275.1"
                               displayName="{Buffered Area
DisplayName}" />
                     </qualifier>
                  </code>

                  <value xsi:type="PQ" nullFlavor="OTH">
                    <translation value="{Buffered Area value}"
                          displayName="{Unit DisplayName}"
                          code="{Unit Code}"
                          codeSystem="2.16.840.1.113883.6.275.1"/>
                  </value>

               </observationCriterion>
            </precondition>
```

5.2.4.4.14   *Max Release Height*

Identifies the maximum distance between the point of release from the application
equipment and the top of crop or ground.

Entry type: value unit.

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Validation Procedures:

5.2.4.4.14.1 There is zero to one Maximum Release Height precondition.

5.2.4.4.14.2 The checkPoint code is 'T'.

5.2.4.4.14.3 The Release Height is a number.

5.2.4.4.14.4 Units must be Standard Length units.

5.2.4.4.14.5 If Max Release Hight is provided at the Product or Scenario Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Max Release Height -->
            <precondition>
               <!-- observation must hold true throughout application -->
               <checkpointCode code="T"/>

               <observationCriterion>
                  <code code="1005327"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Release Height"/>

                  <value xsi:type="PQ" nullFlavor="OTH">
                     <translation value="{Release Height}"
                           displayName="{Unit DisplayName}"
                           code="{Unit Code}"
                           codeSystem="2.16.840.1.113883.6.275.1"/>
                  </value>

               </observationCriterion>
            </precondition>
```

5.2.4.4.15   Max Wind Speed

Identifies the maximum wind speed allowed during application.

Entry type: value unit.

Validation Procedures:

5.2.4.4.15.1 There is zero to one Maximum Wind Speed precondition.

5.2.4.4.15.2 The checkPoint code is 'T'.

5.2.4.4.15.3 The Wind speed is a number.

5.2.4.4.15.4 Units must be speed units.

5.2.4.4.15.5 If Max Wind Speed is provided at the Product or Scenario Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

             <!-- other elements -->

            <!-- (0..1) Max Wind Speed -->
            <precondition>
               <!-- observation must hold true throughout application -->
               <checkpointCode code="T"/>

               <observationCriterion>

                  <code code="1005328"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Windspeed"/>

                  <value xsi:type="PQ" nullFlavor="OTH">
                    <translation value="{Wind Speed}"
                          displayName="{Unit DisplayName}"
                          code="{Unit Code}"
                          codeSystem="2.16.840.1.113883.6.275.1"/>
                  </value>

               </observationCriterion>
            </precondition>
```

5.2.4.4.16 *Temperature Range at Application*

Identifies the minimum and maximum temperatures at which application(s) may be made.

Entry type: value unit, value unit.

Validation Procedures:

5.2.4.4.16.1 There is zero to one Temperature at Application preconditions.
5.2.4.4.16.2 The checkPoint code is 'B'.
5.2.4.4.16.3 The Minimum Temperature is a number.
5.2.4.4.16.4 The Maximum Temperature is a number.
5.2.4.4.16.5 The Minimum and Maximum Temperature units must be Temperature Units.
5.2.4.4.16.6 If Temperature Range at Application is provided at the Product or Scenario Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->
```

```
                    <!-- (0..1) Temperature Range at Application -->
                    <precondition>
                        <!-- observation checked before application -->
                        <checkpointCode code="B"/>

                        <observationCriterion>
                            <code code="1005330"
codeSystem="2.16.840.1.113883.6.275.1"
                                displayName="Temperature Range at Application"/>

                            <value xsi:type="IVL_PQ">
                              <low xsi:type="IVXB_PQ" nullFlavor="OTH">
                                <translation value="{Minimum Temperature}"
                                    displayName="{Unit DisplayName}"
                                    code="{Unit Code}"
                                    codeSystem="2.16.840.1.113883.6.275.1"/>
                              </low>
                              <high xsi:type="IVXB_PQ" nullFlavor="OTH">
                                <translation value="{Maximum Temperature}"
                                    displayName="{Unit DisplayName}"
                                    code="{Unit Code}"
                                    codeSystem="2.16.840.1.113883.6.275.1"/>
                              </high>
                            </value>
                        </observationCriterion>
                    </precondition>
```

5.2.4.4.17   *ASABE Droplet Size* (+)

Identifies restrictions associated with the application droplet size according to the
ASABE 572 standard. Droplet sizes that are acceptable for application should be
selected. This is required for broadcast applications using aerial or ground equipment.

Entry type: "*ASABE Droplet Size*" picklist selection, and value unit.

Validation Procedures:
5.2.4.4.17.1 There is zero to many ASABE requirements.
5.2.4.4.17.2 Required for Type = 'broadcast', Form as Applied = 'liquid
              formations' and Application Equipment = 'Aerial' or 'Groundboom'.
5.2.4.4.17.3 Code is from the list *ASABE Droplet Size*.
5.2.4.4.17.4 DisplayName matches the code.
5.2.4.4.17.5 If ASABE Droplet Size is provided at the Product or Scenario Level,
              then it should not also be provided at the Site level.

Xml Code Snippet:
```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
    <substanceAdministration>
        <componentOf>
            <protocol>

                <!-- other elements -->

                <!-- (0..*) ASABE Droplet Size -->
```

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```
                    <component>
                       <requirement>
                          <code code="1004962"
codeSystem="2.16.840.1.113883.6.275.1"
                                displayName="ASABE Droplet Size">
                             <qualifier xsi:type="CR">
                                <value code="{ASABE Droplet Size Code}"
                                       codeSystem="2.16.840.1.113883.6.275.1"
                                       displayName="{ASABE Droplet Size
DisplayName}"/>
                             </qualifier>
                          </code>
                       </requirement>
                    </component>
```

5.2.4.4.18   Soil Incorporation Depth and Time

Identifies the minimum soil incorporation depth that is required for the application, and
the maximum amount of time that may pass before incorporation takes place. If the
incorporation is done during application, enter the time as "0" minutes.

Entry type: value unit, value unit.

Validation Procedures:

5.2.4.4.18.1 There is zero to one Soil Incorporation Depth and Time
                 observations.
5.2.4.4.18.2 The sequenceNumber value is 3.
5.2.4.4.18.3 The Maximum time after application is a number.
5.2.4.4.18.4 The Maximum time unit is a time unit.
5.2.4.4.18.5 The Minimum depth is a number.
5.2.4.4.18.6 The Minimum depth unit is a Standard Length units.
5.2.4.4.18.7 If Soil Incorporation Depth and time is provided at the Product or
                 Scenario Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Soil Incorporation Min Depth -->
            <component>
               <!-- after application -->
               <sequenceNumber value="3"/>

               <!-- wait some period of time -->
               <pauseQuantity xsi:type="PQ" nullFlavor="OTH">
                 <translation value="{Maximum time after application}"
                         displayName="{Unit DisplayName}"
                         code="{Unit Code}"
                         codeSystem="2.16.840.1.113883.6.275.1"/>
               </pauseQuantity>
```

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```
                    <!-- conduct observation -->
                    <monitoringObservation>
                        <code code="1005331"
codeSystem="2.16.840.1.113883.6.275.1"
                            displayName="Soil Incorporation Depth and Time"/>

                        <precondition>
                            <observationCriterion>
                                <!-- Soil Incorporation Min Depth -->
                                <code code="1005332"
                                    codeSystem="2.16.840.1.113883.6.275.1"
                                    displayName="Soil Incorporation Min
Depth"/>

                                <value xsi:type="IVL_PQ">
                                  <low xsi:type="IVXB_PQ" nullFlavor="OTH">
                                    <translation code="{Unit Code}"
                                            codeSystem="2.16.840.1.113883.6.275.1"
                                            displayName="{Unit DisplayName"
                                            value="{Minimum Depth}"/>
                                  </low>
                                </value>
                            </observationCriterion>
                        </precondition>
                    </monitoringObservation>
                </component>
```

5.2.4.4.19   *Restricted Soil Type* (+)

Identifies any soil type(s) to which the product cannot be applied using these methods.

Entry type: "*Soil Type*" picklist selection, and value unit.

Validation Procedures:

5.2.4.4.19.1 There is zero to many Restricted Soil Type preconditions.
5.2.4.4.19.2 The checkPoint code is 'B'.
5.2.4.4.19.3 Code is from the list *Soil Type*.
5.2.4.4.19.4 DisplayName matches the code.
5.2.4.4.19.5 If Restricted Soil Type is provided at the Product or Scenario Level,
              then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Restricted Soil Type -->
            <precondition>
               <!-- observation checked before application -->
               <checkpointCode code="B"/>
```

```
                <observationCriterion>

                    <code code="1004961"
                          codeSystem="2.16.840.1.113883.6.275.1"
                          displayName="Soil Type"/>

                    <value xsi:type="CD" code="{Restricted Soil Type}"
                           codeSystem="2.16.840.1.113883.6.275.1"
                           displayName="{Restricted Soil Type DisplayName}"
/>

                    <!-- not the condition -->
                    <valueNegationInd value="true"/>

                </observationCriterion>
            </precondition>
```

5.2.4.4.20   Minimum Percent Soil Organic Matter

Identifies the minimum percent soil organic matter to which application(s) may be made.

Entry type: value unit.

Validation Procedures:

5.2.4.4.20.1   There is zero to one Minimum Percent Soil Organic Matter precondition.

5.2.4.4.20.2   The checkPoint code is 'B'.

5.2.4.4.20.3   The Percent Soil value is a number.

5.2.4.4.20.4   The units are Percent (code "3627136") with displayName "%".

5.2.4.4.20.5   If Minimum Percent Soil Organic Matter is provided at the Product or Scenario Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

             <!-- other elements -->

            <!-- (0..1) Minimum Percent Soil Organic Matter -->
            <precondition>

                <!-- observation checked before application -->
                <checkpointCode code="B"/>

                <observationCriterion>

                    <code code="1005333"
codeSystem="2.16.840.1.113883.6.275.1"
                          displayName="Percent Soil Organic Matter"/>

                    <value xsi:type="PQ" nullFlavor="OTH">
```

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```
                        <translation code="3627136"
                                codeSystem="2.16.840.1.113883.6.275.1"
                                displayName="%"
                                value="{Percent Soil Organic Matter}"/>
                    </value>

                </observationCriterion>
            </precondition>
```

5.2.4.4.21   Minimum Age of Animal to be treated

Identifies the minimum age of animals to which application(s) may be made.

Entry type: value unit.

Validation Procedures:

5.2.4.4.21.1 There is zero to one Minimum Age preconditions.

5.2.4.4.21.2 The checkPoint code is 'B'.

5.2.4.4.21.3 The Minimum Age is a number.

5.2.4.4.21.4 Minimum Age units must be time units.

5.2.4.4.21.5 If Minimum Age of Animal to be treated is provided at the Product
              or Scenario Level, then it should not also be provided at the Site
              level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Minimum Age of Animal to be treated -->
            <precondition>
               <!-- observation checked before application -->
               <checkpointCode code="B"/>

               <observationCriterion>
                 <code code="1005334"
                       codeSystem="2.16.840.1.113883.6.275.1"
                       displayName="Minimum Age of Animal to be
treated"/>
                  <value xsi:type="PQ" nullFlavor="OTH">
                    <translation value="{Minimum Age}"
                              displayName="{Units DisplayName}"
                              code="{Minimum Age units}"
                              codeSystem="2.16.840.1.113883.6.275.1"/>
                  </value>
               </observationCriterion>
            </precondition>
```

5.2.4.4.22   *Minimum Weight of Animal to be treated*

Identifies the minimum weight of animals to which application(s) may be made.

Entry type: value unit.

Validation Procedures:

5.2.4.4.22.1 There is zero to one Minimum Weight preconditions.
5.2.4.4.22.2 The checkPoint code is 'B'.
5.2.4.4.22.3 The Minimum Weight is a number.
5.2.4.4.22.4 The Minimum Weight units must be Standard Weight/Capacity units.
5.2.4.4.22.5 If Minimum Weight of Animal is provided at the Product or Scenario Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Minimum Weight of Animal to be treated -->
            <precondition>
               <!-- observation checked before application -->
               <checkpointCode code="B"/>

               <observationCriterion>
                  <code code="1005335 "
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Minimum Weight of Animal"/>

                <value xsi:type="PQ" nullFlavor="OTH">
                  <translation value="{Minimum Weight}"
                          displayName="{Units DisplayName}"
                          code="{Minimum Age units}"
                          codeSystem="2.16.840.1.113883.6.275.1"/>
                </value>
               </observationCriterion>
            </precondition>
```

5.2.4.4.23   *Pollinator* (+)

Identifies specific label restrictions to application based on pollinator protection. The statements selected from the picklist and those that appear on the label must not be identical, but must have the same general meaning.

Entry type: "*Pollinator Protection Statements*" picklist selection.

Validation Procedures:

5.2.4.4.23.1 There is zero to many Pollinator Protection Statement requirements.
5.2.4.4.23.2 Code is from the list *Pollinator Protection Statements*.

5.2.4.4.23.4 If Pollinator is provided at the Product or Scenario Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Pollinator -->
            <component>
               <requirement>
                  <code code="1005022"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Pollinator Protect Statements">
                     <qualifier xsi:type="CR">
                        <value code="{Pollinator Code}"
                               codeSystem="2.16.840.1.113883.6.275.1"
                               displayName="{Pollinator DisplayName}"/>
                     </qualifier>
                  </code>
               </requirement>
            </component>
```

5.2.4.4.24   Bulletins Live

Identifies if there is an Endangered Species County Level Bulletin indicator on the label. This is a presence/absence indicator. If a bulletins live statement appears on the label, then Bulletins Live should be selected.

Entry type: presence/absence selection.

Validation Procedures:
5.2.4.4.24.1 There is zero to one Bulletins Live requirements.
5.2.4.4.24.2 If Bulletins Live is provided at the Product or Scenario Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Bulletins Live -->
            <component>
               <requirement>
```

```
                    <code code="1005336"
codeSystem="2.16.840.1.113883.6.275.1"
                             displayName="Bulletins Live"/>
                    </requirement>
                </component>
```

5.2.4.4.25   *Applications to Water* (+)

Identifies specific label a restrictions related to the treatment of a volume of water
(includes flooded field applications and waterbodies). The statements selected from the
picklist and those that appear on the label must not be identical, but must have the same
general meaning.

> **Entry type:** "*Water Protection Statements*" picklist selection.

> **Validation Procedures:**
> 5.2.4.4.25.1 There is zero to many Applications to Water requirements.
> 5.2.4.4.25.2 Code is from the list *Water Protection Statements*.
> 5.2.4.4.25.3 DisplayName matches the code.
> 5.2.4.4.25.4 If Application to Water is provided at the Product or Scenario Level,
> then it should not also be provided at the Site level.

> **Xml Code Snippet:**

```xml
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Applications to Water -->
            <component>
                    <requirement>
                  <code code="1005023"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Water Protection Statement">
                     <qualifier xsi:type="CR">
                        <value code="{Water Protection Statement Code}"
                               codeSystem="2.16.840.1.113883.6.275.1"
                               displayName="{Water Protection Statement
DisplayName}"/>
                     </qualifier>
                  </code>
               </requirement>
            </component>
```

5.2.4.4.26   *Secondary Manufacturing*

Identifies if there are any restrictions which limit further manufacturing of the treated
material. This is a presence/absence indicator. If any restrictions limiting secondary
manufacture appear on the label, then Secondary Manufacture should be selected.

> **Entry type:** presence/absence selection.

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Validation Procedures:

5.2.4.4.26.1 There is zero to one Secondary Manufacturing requirements.

5.2.4.4.26.2 If Secondary Manufacturing is provided at the Product or Scenario
Level, then it should not also be provided at the Site level

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- Secondary Manufacturing -->
            <component>
               <requirement>
                  <code code="1005337"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Secondary Manufacturing"/>
               </requirement>
            </component>
```

5.2.4.4.27   *Restricted Use Site Location* (+)

Identifies if applications are not permitted in specific Use Site Locations. Locations
entered as restricted cannot be entered as permitted in scenario attribute sections at lower
levels of the model. Generally, elements that are not positively entered in the attributes
section of this document are considered to be disallowed. This restriction should only be
entered if the text of the label explicitly prohibits this type of application.

Entry type: "*Use Site Location*" picklist selection.

Validation Procedures:

5.2.4.4.27.1 There is zero to many Restricted Use Location preconditions.

5.2.4.4.27.2 The checkpointCode code is 'B'.

5.2.4.4.27.3 Code is from the list *Use Site Location*.

5.2.4.4.27.4 DisplayName matches the code.

5.2.4.4.27.5 If Restricted Use Site Location is provided at the Product or Scenario
Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->
```

```
              <!-- (0..*) Restricted Locations -->
              <precondition>
                 <!-- observation checked before application -->
                 <checkpointCode code="B"/>

                 <observationCriterion>
                     <code code="1004663"
codeSystem="2.16.840.1.113883.6.275.1"
                            displayName="Use Site Location"/>

                     <value xsi:type="CD" code="{Use Site Location Code}"
        codeSystem="2.16.840.1.113883.6.275.1"
                            displayName="{Use Site Location DisplayName}"/>

                     <!-- not the condition -->
                     <valueNegationInd value="true"/>
                 </observationCriterion>
              </precondition>
```

5.2.4.4.28   Restricted Application Target (+)

Identifies if applications are not permitted to specific targets. Targets entered as restricted cannot be entered as permitted in scenario attribute sections at lower levels of the model. Generally, elements that are not positively entered in the attributes section of this document are considered to be disallowed. This restriction should only be entered if the text of the label explicitly prohibits this type of application.

Entry type: "*Application Target*" picklist selection.

Validation Procedures:

5.2.4.4.28.1 There is zero to many Restricted Application Target preconditions.
5.2.4.4.28.2 The checkpointCode code is 'B'.
5.2.4.4.28.3 Code is from the list *Application Target*.
5.2.4.4.28.4 DisplayName matches the code.
5.2.4.4.28.5 If Restricted Use Site Location is provided at the Product or Scenario Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Restricted Application Target -->
            <precondition>
               <!-- observation checked before application -->
               <checkpointCode code="B"/>

               <observationCriterion>

                  <code code="1004682"
```

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```
codeSystem="2.16.840.1.113883.6.275.1"
                         displayName="Application Target"/>

                  <value xsi:type="CD" code="{Application Target Code}"
        codeSystem="2.16.840.1.113883.6.275.1"
                         displayName="{Application Target DisplayName}"/>

                  <!-- not the condition -->
                  <valueNegationInd value="true"/>
               </observationCriterion>
            </precondition>
```

5.2.4.4.29   *Restricted Application Type* (+)

Identifies if applications are not permitted using specific application types. Application types entered as restricted cannot be entered as permitted in scenario attribute sections at lower levels of the model. Generally, elements that are not positively entered in the attributes section of this document are considered to be disallowed. This restriction should only be entered if the text of the label explicitly prohibits this type of application.

Entry type: "*Application Type*" picklist selection.

Validation Procedures:

5.2.4.4.29.1 There is zero to many Restricted Application Type preconditions.
5.2.4.4.29.2 The checkpointCode code is 'B'.
5.2.4.4.29.3 Code is from the list *Application Type*.
5.2.4.4.29.4 DisplayName matches the code.
5.2.4.4.29.5 If Restricted Application Type is provided at the Product or Scenario Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Restricted Application Type -->
            <precondition>
               <!-- observation checked before application -->
               <checkpointCode code="B"/>

               <observationCriterion>

                  <code code="1004920"
codeSystem="2.16.840.1.113883.6.275.1"
                         displayName="Application Type"/>

                  <value xsi:type="CD" code="{Application Type Code}"
        codeSystem="2.16.840.1.113883.6.275.1"
```

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```
                              displayName="{Application Type DisplayName}"/>

                    <!-- not the condition -->
                    <valueNegationInd value="true"/>
                </observationCriterion>
            </precondition>
```

5.2.4.4.30 *Restricted Application Equipment* (+)

Identifies if applications are not permitted using specific equipment. Equipment entered as restricted cannot be entered as permitted in scenario attribute sections at lower levels of the model. Generally, elements that are not positively entered in the attributes section of this document are considered to be disallowed. This restriction should only be entered if the text of the label explicitly prohibits this type of application.

Entry type: "*Application Equipment*" picklist selection.

Validation Procedures:

5.2.4.4.30.1 There is zero to many Restricted Application Equipment preconditions.
5.2.4.4.30.2 The checkpointCode code is 'B'.
5.2.4.4.30.3 Code is from the list *Application Equipment*.
5.2.4.4.30.4 DisplayName matches the code.
5.2.4.4.30.5 If Restricted Application Equipment is provided at the Product or Scenario Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
    <substanceAdministration>
        <componentOf>
            <protocol>

                <!-- other elements -->

                <!-- (0..*) Restricted Application Equipment -->
                <precondition>
                    <!-- observation checked before application -->
                    <checkpointCode code="B"/>

                    <observationCriterion>
                        <code code="1004922"
codeSystem="2.16.840.1.113883.6.275.1"
                            displayName="Application Equipment"/>

                        <value xsi:type="CD" code="{Application Equipment
Code}"

        codeSystem="2.16.840.1.113883.6.275.1"
                            displayName="{Application Equipment
DisplayName}"/>

                        <!-- not the condition -->
                        <valueNegationInd value="true"/>
```

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```
            </observationCriterion>
        </precondition>
```

5.2.4.4.31 *Restricted Application Timing* (+)

Identifies if applications are not permitted during specific timings. Timings entered as restricted cannot be entered as permitted in scenario attribute sections at lower levels of the model. Generally, elements that are not positively entered in the attributes section of this document are considered to be disallowed. This restriction should only be entered if the text of the label explicitly prohibits this type of application.

Entry type: "*Application Timing (Time of Day)"," Application Timing (Timing of Pest)", and/or "Application Timing (Use Site Status)*" picklist selection.

Validation Procedures:

5.2.4.4.31.1 There is zero to many Restricted Application Timing (Time of Day), Restricted Application Time (Timing of Pest) or Application Timing (Use Site Status) preconditions.
5.2.4.4.31.2 The checkpointCode code is 'B'.
5.2.4.4.31.3 The Application Timing Code is defined in the appropriate *Application Timing (Time of Day), Application Timing (Timing of Pest) or Application Timing (Use Site Status)* list
5.2.4.4.31.4 DisplayName matches the code.
5.2.4.4.31.5 If Restricted Application Timing is provided at the Product or Scenario Level, then it should not also be provided at the Site level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
        <protocol>

           <!-- other elements -->

           <!-- (0..*) Restricted App Timing (Time of Day) -->
           <precondition>
              <!-- observation checked before application -->
              <checkpointCode code="B"/>

              <observationCriterion>
                  <code code="1004921"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Application Timing (Time of Day)"/>

                  <value xsi:type="CD" code="{Application Timing Code}"
      codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="{Application Timing DisplayName}"/>

                  <!-- not the condition -->
                  <valueNegationInd value="true"/>
```

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```
                </observationCriterion>
             </precondition>

             <!-- (0..*) Restricted App Timing -->
             <precondition>
                <!-- observation checked before application -->
                <checkpointCode code="B"/>

                <observationCriterion>
                   <code code="1005020"
codeSystem="2.16.840.1.113883.6.275.1"
                         displayName="Application Timing (Timing of
Pest)"/>

                   <value xsi:type="CD" code="{Application Timing Code}"
        codeSystem="2.16.840.1.113883.6.275.1"
                         displayName="{Application Timing DisplayName}"/>

                   <!-- not the condition -->
                   <valueNegationInd value="true"/>
                </observationCriterion>
             </precondition>

             <!-- (0..*) Restricted App Timing -->
             <precondition>
                <!-- observation checked before application -->
                <checkpointCode code="B"/>

                <observationCriterion>
                   <code code="1004960"
codeSystem="2.16.840.1.113883.6.275.1"
                         displayName="{Application Timing (Use Site
Status)}"/>

                   <value xsi:type="CD" code="{Application Timing Code}"
        codeSystem="2.16.840.1.113883.6.275.1"
                         displayName="{Application Timing DisplayName}"/>

                   <!-- not the condition -->
                   <valueNegationInd value="true"/>
                </observationCriterion>
             </precondition>
```

5.2.5 Scenario Level (+)

The "Scenario Level" section is a "Site Level" subsection and is a header section to contain the child sections defined herein. The "Scenario Level" section can be repeated to create many scenario level sections within a "Site Level" section.

A scenario describes specific instructions for how to use the product. Each Scenario is defined as a Scenario Rate pattern (including both single and yearly rates) and all the Scenario Attributes (target, timing, type, equipment, and associated restrictions) by which that rate can be applied.

While most of the rates on labels are presented in terms of a particular pest, the goal of the Scenarios is to capture the maximum overall rate for the method at a particular Site.

The system is flexible in that if all of the Scenario Rate elements are identical, then multiple Scenario Attributes may be listed as a single Scenario. Likewise, if a label has more complicated application instructions, then additional Scenarios can be added to isolate caveats to the maximum use. This may also include use of the "Geographic Restriction" when rates differ based on geography, or other restrictions. Before entering information to define a Scenario, look across the application instructions for the Site to determine if there are unique use pattern parameters. For example, if there are different application rates associated with a pre-plant, soil in-furrow application vs. a post emergent foliar application, then a separate scenario is entered for each. Similarly, if the parameters do not change with variations in equipment, timing, application type, or target, then a single Scenario can capture all the details by simply selecting multiple values from the picklists. It is important to remember, however, that all combination of these selections must be allowable.

Information entered in the Scenario Level subsections applies to all combinations of Scenario Attributes listed.

Validation Procedures:

5.2.5.1.1.1   There is at least one "Scenario Level" section per "Site Level" section.
5.2.5.1.1.2   The section title is the same as the section code displayName.
5.2.5.1.1.3   The section link is optional.
5.2.5.1.1.4   If the section link is provided then the section link is a unique string within the document.
5.2.5.1.1.5   The section id is a unique UUID within the document.

Xml Code Snippet:

```
<component>
   <section ID="{Section Link}">
      <id root="{Section Id}"/>
      <code code="3810091" codeSystem="2.16.840.1.113883.6.275.1"
            displayName="Scenario Level"/>
      <title>Scenario Level</title>
```

5.2.5.2   Scenario Rate

Describes single and yearly/crop cycle maximum rate parameters that can be applied using a set of Scenario Attributes. Only one set of maximum single and yearly/crop cycle rates may be entered for each Scenario. Differences in these values (except minimum rate) trigger a new Scenario. Each Scenario must contain a single maximum application rate, and at least one number of application per year/crop cycle or maximum rate per year/crop cycle.

Validation Procedures:

5.2.5.2.1.1   There is one "Scenario Rate" section per "Scenario Level" section.
5.2.5.2.1.2   The section title is the same as the section code displayName.

5.2.5.2.1.3   The section link is optional.
5.2.5.2.1.4   If the section link is provided then the section link is a unique string within the document.
5.2.5.2.1.5   The section id is a unique UUID within the document.
5.2.5.2.1.6   Scenario Rate must be less then the Use Site Yearly Rate when Unit of Measure codes are the same.

Xml Code Snippet:

```
<component>
   <section ID="{Section Link}">
      <id root="{Section Id}"/>
      <code code="3810092" codeSystem="2.16.840.1.113883.6.275.1"
            displayName="Scenario Rate"/>
      <title>Scenario Rate</title>
```

5.2.5.2.2 *Single Application Rate Range*

The single application rate is entered in as a numerical range of pesticide quantity per an area, volume, time, or target of application. The value range is represented as the **Single Application Minimum Rate** and the **Single Application Maximum Rate**. For the purposes of this document, we will define the single application rate as the quantity of product that can be applied per day (24 hrs.) to the Site using the Scenario. Minimum values are only required for scenarios that require efficacy data (such as public health uses).

While rates on labels are frequently presented in terms of a particular pest, the goal of the Single Application Rate Range is to capture the minimum and maximum overall rate for that can be applied with a particular combination of Scenario Attributes.

Typically, for conventional pesticide uses, rates will be expressed in terms of amount of product per area treated. Some rates, however, will require non-area based units (such as per 100 lbs of seed, per animal, per volume, or per second).

Typically, for antimicrobial uses, rates will be expressed in terms of amount of product per amount of treated material or as a target concentration (such as ppm or % based on total product weight).

Additionally, rates may be entered here as dilution quantities (amount of product per minimum volume of diluent) if the maximum volume of the resulting finish spray that can be applied per area is listed in the Minimum Diluent Volume or Maximum Finish Spray Volume per Area entry point below. If the denominator of the rate given here is a volume, and the Application Target is not water or a treated material, then it will be assumed that the value entered in the "Minimum Diluent Volume or Maximum Finish Spray Volume per Area" entry point is in terms of the finish spray.

Entry type: value unit - value unit.

Validation Procedures:

5.2.5.2.2.1   There is one Maximum Single Application Rate characteristic.

5.2.5.2.2.2   There is zero to one Minimum Single Application Rate characteristic.

5.2.5.2.2.3   The xsi:type of Minimum, if provided and Maximum Single Application Rate "s "RTO_PQ"PQ".

5.2.5.2.2.4   The Maximum rate is a number.

5.2.5.2.2.5   Both Maximum and Minimum numerator units must match.

5.2.5.2.2.6   Both Maximum and Minimum denominator units must match.

5.2.5.2.2.7   The Minimum rate, if provided is a number.

5.2.5.2.2.8   Minimum and Maximum Single Application Rate numerator units must be one of the following:

- Standard Weight / Mass
- Standard Volume / Capacity
- Miscellaneous Application Unit
- Concentration
- Non-Standard Volume / Capacity

5.2.5.2.2.9   Minimum, if provided and Maximum Single Application Rate denominator units must be one of the following:

- Standard Area
- Standard Length
- Standard Weight / Mass
- Standard Volume / Capacity
- Time
- Blank (if numerator is Concentration)
- Non-Standard Volume / Capacity
- Non-standard - Target (with acreage rate limit)
- Non-Standard Weight / Mass
- Miscellaneous – Target

Xml Code Snippet:

```
<title>Scenario Rate</title>
<subject2>
   <substanceAdministration>

      <!-- Minimum Single Application Rate -->
      <subjectOf>
        <characteristic>
          <code code="1005314" codeSystem="2.16.840.1.113883.6.275.1"
                displayName="Minimum Single Application Rate"/>
          <value xsi:type="RTO_PQ_PQ">
             <numerator xsi:type="PQ" nullFlavor="OTH">
                <translation value="{Minimum Rate}"
                    code="{Unit Code}"
                    codeSystem="2.16.840.1.113883.6.275.1"
                    displayName="{Unit DisplayName}"/>
             </numerator>
```

```
                    <denominator xsi:type="PQ" nullFlavor="OTH">
                      <translation value="{Per Quantity}"
                          code="{Unit Code}"
                          codeSystem="2.16.840.1.113883.6.275.1"
                          displayName="{Unit DisplayName}"/>
                    </denominator>
                </value>
            </characteristic>
        </subjectOf>

        <!-- Maximum Single Application Rate -->
        <subjectOf>
            <characteristic>
                <code code="1005315" codeSystem="2.16.840.1.113883.6.275.1"
                    displayName="Maximum Applications per Site"/>
                <value xsi:type="RTO_PQ_PQ">
                    <numerator xsi:type="PQ" nullFlavor="OTH">
                      <translation value="{Maximum Rate}"
                          code="{Unit Code}"
                          codeSystem="2.16.840.1.113883.6.275.1"
                          displayName="{Unit DisplayName}"/>
                    </numerator>
                    <denominator xsi:type="PQ" nullFlavor="OTH">
                      <translation value="{Per Quantity}"
                          code="{Unit Code}"
                          codeSystem="2.16.840.1.113883.6.275.1"
                          displayName="{Unit DisplayName}"/>
                    </denominator>
                </value>
            </characteristic>
        </subjectOf>
```

5.2.5.2.3 *Acre Rate for Non-Standard Target Measures*

The acre rate for non-standard target measures identifies the mass of product that can be applied per day (24 hrs.) using this Scenario, when non-standard target units are used for the single application rate. For example, if a rate is expressed as amount of product per insect mound, per acre rate is needed to clarify the extent of allowable use. This information must be supplied if "Non-Standard Target" application units are used for Single Application Rates (see units terminology for a complete listing of these units). Non-standard target application units may not be used for yearly or crop cycle application rates.

Entry type: value unit per value unit.

Validation Procedures:

5.2.5.2.3.1   There is zero to one Acre Rate for Non-Standard Target Measures characteristics.

5.2.5.2.3.2   The xsi:type of Acre Rate for Non-Standard Target Measures "s "RTO_PQ"PQ".

5.2.5.2.3.3   Acre Rate for Non-Standard Target Measures is required if the units used in Single Application Rate are Non-standard target (with acreage rate limit) units.

5.2.5.2.3.4   The Acre rate is a number.

5.2.5.2.3.5   Numerator units must be one of the following:

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- Standard Weight / Mass
- Standard Volume / Capacity
- Miscellaneous Application Unit
- Concentration
- Non-Standard Volume / Capacity

5.2.5.2.3.6   Denominator units must be one of the following:

- Standard Area
- Standard Length
- Standard Weight / Mass
- Standard Volume / Capacity
- Time
- Blank (if numerator is Concentration)
- Non-Standard Volume / Capacity
- Non-standard - Target (with acreage rate limit)
- Non-Standard Weight / Mass
- Miscellaneous – Target

Xml Code Snippet:

```
<title>Scenario Rate</title>
<subject2>
   <substanceAdministration>

      <!-- Acre Rate -->
      <subjectOf>
        <characteristic>
          <code code="1005316" codeSystem="2.16.840.1.113883.6.275.1"
                displayName="Acre rate"/>

          <value xsi:type="RTO_PQ_PQ">
            <numerator xsi:type="PQ" nullFlavor="OTH">
              <translation value="{Acre Rate}"
                      code="{Unit Code}"
                      codeSystem="2.16.840.1.113883.6.275.1"
                      displayName="{Unit DisplayName}"/>
            </numerator>
            <denominator xsi:type="PQ" nullFlavor="OTH">
              <translation value="{Per Quantity}"
                      code="{Unit Code}"
                      codeSystem="2.16.840.1.113883.6.275.1"
                      displayName="{Unit DisplayName}"/>
            </denominator>
          </value>
        </characteristic>
      </subjectOf>
```

5.2.5.2.4 Minimum Diluent/Carrier or Maximum Finish Spray Amount per Area

Identifies either the minimum volume of diluent/carrier, or the maximum amount of finish spray solution that can be used per treated area. The amount entered may represent

a liquid carrier or a solid carrier (e.g. dry bulk fertilizer). When the Form as Applied data element entry is liquid and nothing is entered in this field it signifies that the product does not need to be diluted prior to application (i.e., is in a ready-to-use form).

Entry type: value unit per value unit.

Validation Procedures:

5.2.5.2.4.1   There is zero to one Minimum Diluent characteristics.
5.2.5.2.4.2   The xsi:type of Minimum Diluent is "RTO_PQ_PQ".
5.2.5.2.4.3   Minimum Diluent is required for liquid form as applied.
5.2.5.2.4.4   Diluent volume is a number.
5.2.5.2.4.5   Diluent volume units must be one of the following:
- Standard/Volume Capacity
- Standard Weight / Mass.

5.2.5.2.4.6   Per Quantity value is a number.
5.2.5.2.4.7   Per Quantity units must be one of the following:

- Standard Area
- Standard Length
- Standard Weight / Mass
- Standard Volume / Capacity
- Non-Standard Volume / Capacity
- Non-standard - Target (with acreage rate limit)
- Non-Standard Weight / Mass
- Miscellaneous – Target

Xml Code Snippet:

```
<title>Scenario Rate</title>
<subject2>
   <substanceAdministration>

      <!-- other elements -->

      <!-- Minimum Diluent Volume per Area -->
      <subjectOf>
        <characteristic>
          <code code="1005317 " codeSystem="2.16.840.1.113883.6.275.1"
                displayName="Minimum Diluent Volume per area"/>

          <value xsi:type="RTO_PQ_PQ">
            <numerator xsi:type="PQ" nullFlavor="OTH">
              <translation value="{Minimum Diluent}"
                      code="{Unit Code}"
                      codeSystem="2.16.840.1.113883.6.275.1"
                      displayName="{Unit DisplayName}"/>
            </numerator>
            <denominator xsi:type="PQ" nullFlavor="OTH">
              <translation value="{Per Quantity}"
                      code="{Unit Code}"
                      codeSystem="2.16.840.1.113883.6.275.1"
                      displayName="{Unit DisplayName}"/>
            </denominator>
          </value>
```

```
            </characteristic>
        </subjectOf>
```

5.2.5.2.5 Residence/contact time

Identifies the minimum time required for the dosage to remain in place. This value is generally associated with efficacy.

Entry type: value unit.

Validation Procedures:

5.2.5.2.5.1   There is zero to one Residence/Contact Time characteristic.
5.2.5.2.5.2   The Residence/Contact Time xsi:type is "PQ".
5.2.5.2.5.3   Residence/Contact Time is required for products where contact time is required for efficacy.
5.2.5.2.5.4   Residence/Contact Time is a number.
5.2.5.2.5.5   Units must be Time units.

Xml Code Snippet:

```
<title>Scenario Rate</title>
<subject2>
   <substanceAdministration>

      <!-- other elements -->

      <!-- Minimum time required for the dosage to remain in place -->
      <subjectOf>
         <characteristic>
            <code code="1005318" codeSystem="2.16.840.1.113883.6.275.1"
                  displayName="Minimum time required"/>
            <value xsi:type="PQ" nullFlavor="OTH">
              <translation value="{Minimum Time}"
                  displayName="{Unit DisplayName}"
                  code="{Unit Code}"
                  codeSystem="2.16.840.1.113883.6.275.1"/>
            </value>
         </characteristic>
      </subjectOf>
```

5.2.5.2.6 Maximum Number of Applications per Scenario per Time

Identifies the maximum number of times the product can be applied per year/crop cycle for this scenario. This value may not exceed the maximum number of applications allowed for the Use Site using all Scenarios (as indicated in Maximum Number of Applications per Site per Time).

Enter information for this and Maximum Application Rate Range per Scenario per Time as either per year or per crop cycle, not a combination of both.

If the maximum number of applications or the maximum application rate are expressed in terms of per crop cycle, the maximum number of crop cycles per year must be recorded using the "Maximum Number of Crop Cycles per Year" field below.

Entry type: value per "*Application Rate Measurement Period*" picklist selection.

Validation Procedures:

5.2.5.2.6.1   At least one of the following "Maximum Number of Application per Scenario per Time" or "Maximum Application Rate Range per Scenario per Time" is required.

5.2.5.2.6.2   Maximum Number of Application per Scenario per Time xsi:type is "PQ".

5.2.5.2.6.3   The Maximum Number of Applications value is a number.

5.2.5.2.6.4   The Maximum Number of Applications unit is 1 (meaning each).

5.2.5.2.6.5   Method code is from the Application Rate Measurement Period list.

Xml Code Snippet:

```
<title>Scenario Rate</title>
<subject2>
   <substanceAdministration>

      <!-- other elements -->

      <componentOf>
         <protocol>
            <component>
               <substanceAdministration>

                  <!-- Maximum Number of Applications per Scenario per
Time -->
                  <subjectOf>

                     <characteristic>
                        <code code="1005319"
                              codeSystem="2.16.840.1.113883.6.275.1"
                              displayName="Maximum Applications "/>
                        <value xsi:type="PQ"
                               value="{Maximum Number}"
                               unit="1"/>
                        <methodCode code="{Method Code}"
                                    codeSystem="2.16.840.1.113883.6.275.1"
                                    displayName="{DisplayName}"/>
                     </characteristic>
                  </subjectOf>
```

5.2.5.2.7 *Maximum Application Rate Range per Scenario per Time*

The maximum yearly/crop cycle application rate is entered in as a numerical range with a given unit per a value with a unit. The value range represents the minimum and maximum cumulative application rate. Minimum values are only required for scenarios that require efficacy data (such as public health uses).

Enter information for this and the previous data element as either per year or per crop cycle, not a combination of both.

If the maximum number of applications or the maximum application rate are expressed in terms of per crop cycle, the maximum number of crop cycles per year must be recorded using the "Maximum Number of Crop Cycles per Year" field.

Entry type: value unit per value unit "*Application Rate Measurement Period*" picklist selection.

Validation Procedures:

5.2.5.2.7.1 At least one of the following "Maximum Number of Application per Scenario per Time" or "Maximum Application Rate Range per Scenario per Time" is required.

5.2.5.2.7.2 Minimum, if provided and Maximum Application Rate xsi:type is "RTO_PQ_PQ" and nullFlavor is "OTH".

5.2.5.2.7.3 Numerator and denominator units in minimum and maximum must match.

5.2.5.2.7.4 The Minimum, if provided and Maximum Application Rate numerator and denominator value is a number.

5.2.5.2.7.5 The Minimum, if provided and Maximum Application Rate numerator units must be one of the following:

- Standard Weight / Mass
- Standard Volume / Capacity
- Miscellaneous Application Unit
- Concentration
- Non-Standard Volume / Capacity

5.2.5.2.7.6 The Minimum, if provided and Maximum Application Rate denominator units must be one of the following:

- Standard Area
- Standard Length
- Standard Weight / Mass
- Standard Volume / Capacity
- Time
- Blank (if numerator is Concentration)
- Non-Standard Volume / Capacity
- Non-standard - Target (with acreage rate limit)
- Non-Standard Weight / Mass
- Miscellaneous – Target

5.2.5.2.7.7 Method code is from the Application Rate Measurement Period list.

Xml Code Snippet:

```
<title>Scenario Rate</title>
<subject2>
```

```
    <substanceAdministration>

        <!-- other elements -->
      <componentOf>
         <protocol>
            <component>
               <substanceAdministration>

                  <!-- other elements -->

                  <!-- Minimum Application Rate Range per Scenario per
time -->
                  <subjectOf>
                     <characteristic>
                        <code code="1005320"
                            codeSystem="2.16.840.1.113883.6.275.1"
                            displayName="Minimum Application Rate"/>
                        <value xsi:type="RTO_PQ_PQ">
                           <numerator xsi:type="PQ" nullFlavor="OTH">
                             <translation value="{Minimum Rate}"
                                 displayName="{Unit DisplayName}"
                                 code="3627132"
                                 codeSystem="2.16.840.1.113883.6.275.1"/>
                           </numerator>
                           <denominator xsi:type="PQ" nullFlavor="OTH">
                             <translation value="{Per Quantity}"
                                 displayName="{Unit DisplayName}"
                                 code="{Unit Code}"
                                 codeSystem="2.16.840.1.113883.6.275.1"/>
                           </denominator>
                        </value>
                        <methodCode code="{Method Code}"
                              codeSystem="2.16.840.1.113883.6.275.1"
                              displayName="{DisplayName}"/>
                     </characteristic>
                  </subjectOf>

                  <!-- Maximum Application Rate Range per Scenario per
time -->
                  <subjectOf>
                     <characteristic>
                        <code code="1005321"
                            codeSystem="2.16.840.1.113883.6.275.1"
                            displayName="Maximum Application Rate"/>
                        <value xsi:type="RTO_PQ_PQ">
                           <numerator xsi:type="PQ" nullFlavor="OTH">
                             <translation value="{Maximum Rate}"
                                 displayName="{Unit DisplayName}"
                                 code="3627132"
                                 codeSystem="2.16.840.1.113883.6.275.1"/>
                           </numerator>
                           <denominator xsi:type="PQ" nullFlavor="OTH">
                             <translation value="{Per Quantity}"
                                 displayName="{Unit DisplayName}"
                                 code="{Unit Code}"
                                 codeSystem="2.16.840.1.113883.6.275.1"/>
                           </denominator>
                        </value>
                        <methodCode code="{Method Code}"
                              codeSystem="2.16.840.1.113883.6.275.1"
                              displayName="{DisplayName}"/>
                     </characteristic>
                  </subjectOf>
```

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5.2.5.2.8 *Maximum Number of Crop Cycles per Year*

Identifies the number of crop cycles per 12 month (annual) period. This indicator is necessary when rates at the Use Site or Scenario level are based on a crop cycle rather than year.

> **Entry type:** value per "*Application Rate Measurement Period*" picklist selection.

> **Validation Procedures:**
> 5.2.5.2.8.1 There is zero to one Maximum Number of Crop Cycles per Year characteristics.
> 5.2.5.2.8.2 Maximum Number of Crop Cycles per Year is required if rates are given by crop cycle on the label for this site.
> 5.2.5.2.8.3 Maximum number of crop cycles is a number.
> 5.2.5.2.8.4 Maximum number of crop cycles unit is per year (with code "3627146" with displayName = "year").

> **Xml Code Snippet:**

```
<title>Scenario Rate</title>
<subject2>
   <substanceAdministration>

      <!-- other elements -->

      <componentOf>
         <protocol>
            <component>
               <substanceAdministration>

                  <!-- other elements -->

                  <!-- Maximum Number of Crop Cycles per Year -->
                  <subjectOf>
                     <characteristic>
                       <code code="1005322"
                           codeSystem="2.16.840.1.113883.6.275.1"
                           displayName="Max Num Crop Cycles per Year"/>
                       <value xsi:type="PQ" nullFlavor="OTH">
                         <translation code="3627146"
                                codeSystem="2.16.840.1.113883.6.275.1"
                                displayName="year"
                                value="{Max Num Crop Cycles Value}"/>
                       </value>
                     </characteristic>
                  </subjectOf>
```

5.2.5.3 Scenario Attributes

Identifies the method(s) in which a single set of rate parameters can be applied. Multiple scenario attributes can be entered for each rate parameter set if all of the use pattern parameters and restrictions/limitations are identical.

<u>Validation Procedures:</u>

5.2.5.3.1.1 There is one "Scenario Attributes" section per "Scenario Level" section.
5.2.5.3.1.2 The section title is the same as the section code displayName.
5.2.5.3.1.3 The section link is optional.
5.2.5.3.1.4 If the section link is provided then the section link is a unique string within the document.
5.2.5.3.1.5 The section id is a unique UUID within the document.

<u>Xml Code Snippet:</u>

```
<component>
   <section ID="{Section Link}">
      <id root="{Section Id}"/>
      <code code="3810093" codeSystem="2.16.840.1.113883.6.275.1"
            displayName="Scenario Attributes"/>
      <title>Scenario Attributes</title>
```

5.2.5.3.2 *Form As Applied*

Identifies the form of the product at the time of application. This value may be the same or different from the form as packaged, depending on whether the product is mixed before application or undergoes a physical state change during application.

<u>Entry type:</u> *"Physical Form"* picklist selection.

<u>Validation Procedures:</u>

5.2.5.3.2.1 There is one formCode.
5.2.5.3.2.2 Form code is from the list *Physical Form*.
5.2.5.3.2.3 Display name matches the code.

<u>Xml Code Snippet:</u>

```
<title>Scenario Attributes</title>
<subject2>
   <substanceAdministration>
      <!--  (1..1) Form as Applied -->
      <consumable>
        <administerableMaterial>
           <administrableProduct>
              <formCode code="{Form Code}"
                     codeSystem="2.16.840.1.113883.6.275.1"
                     displayName="{Form Code DisplayName}"/>
           </administrableProduct>
        </administerableMaterial>
      </consumable>
```

5.2.5.3.3 *Application Target* (+)

Identifies what is physically being treated during application/where application is directed (For example foliage/plant, soil, human/animal, etc.).

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Entry type: *"Application Target"* picklist selection.

Validation Procedures:

5.2.5.3.3.1   There is one to many Application Target targetSiteCodes.
5.2.5.3.3.2   Application Target code is from the list *Application Target*.
5.2.5.3.3.3   Display name matches the code.
5.2.5.3.3.4   Application Target code cannot be a code restricted in Product Level
or Site Level.

Xml Code Snippet:

```
<title>Scenario Attributes</title>
<subject2>
   <substanceAdministration>

      <!-- other elements -->

      <!-- (1..*) Application Target -->
      <targetSiteCode code="{Application Target}"
                      codeSystem="2.16.840.1.113883.6.275.1"
                      displayName="{Application Target DisplayName}"/>
```

5.2.5.3.4 Application Type (+)

Identifies the specific method of pesticide application (For example broadcast, dip
treatment, material incorporation, etc.).

Entry type: *"Application Type"* picklist selection.

Validation Procedures:

5.2.5.3.4.1   There is one to many Application Type methodCodes.
5.2.5.3.4.2   Application Type code is from the list *Application Type*.
5.2.5.3.4.3   Display name matches the code.
5.2.5.3.4.4   Application Type code cannot be a code restricted in Product Level
or Site Level.

Xml Code Snippet:

```
<title>Scenario Attributes</title>
<subject2>
   <substanceAdministration>

      <!-- other elements -->

      <!-- (1..*) Application Type -->
      <methodCode code="{Application Type Code}"
                  codeSystem="2.16.840.1.113883.6.275.1"
                  displayName="{Application Type DisplayName}"/>
```

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5.2.5.3.5 *Application Equipment* (+)

Identifies the type of equipment used to apply the product (For example helicopter, trap/bait station, total-release fogger, etc.).

Entry type: *"Application Equipment"* picklist selection.

Validation Procedures:

5.2.5.3.5.1 There is one to many Application Equipment characteristics.
5.2.5.3.5.2 Application Equipment code is from the list *Application Equipment*.
5.2.5.3.5.3 Display name matches the code.
5.2.5.3.5.4 The value xsi:type is "SXCM_CD".
5.2.5.3.5.5 The operator attribute is "I".
5.2.5.3.5.6 Application Equipment code cannot be a code restricted in Product Level or Site Level.

Xml Code Snippet:

```xml
<title>Scenario Attributes</title>
<subject2>
   <substanceAdministration>

      <!-- other elements -->

      <!-- (1..*) Application Equipment -->
      <subjectOf>
         <characteristic>

            <code code="1004922" codeSystem="2.16.840.1.113883.6.275.1"
                  displayName="Application Equipment"/>

            <value xsi:type="SXCM_CD" operator="I"
                   code="{Application Equipment}"
                   codeSystem="2.16.840.1.113883.6.275.1"
                   displayName="{Application Equipment DisplayName}"/>
         </characteristic>
      </subjectOf>
```

5.2.5.3.6 *Application Timing (Site Status)* (+)

Identifies when pesticide application occurs in relation to the use site (For example At Transplant, During Bloom, When Crop is Dormant, etc.). If timing is determined solely by pest pressure, enter "All crop/site stages possible (e.g., timing determined solely by pest pressure)" and then enter the specific pest related timing in Application Timing (Pest).

Entry type: *"Application Timing (Site Status)"* picklist selection.

Validation Procedures:

5.2.5.3.6.1 There is one to many Application Timing (Site Status) code characteristics.
5.2.5.3.6.2 Application Timing (Site Status) code is from the list *Application Timing (Site Status)*.

5.2.5.3.6.3   Display name matches the code.
5.2.5.3.6.4   The value xsi:type is "SXCM_CD" meaning a set of codes.
5.2.5.3.6.5   The operator attribute is "I" meaning inclusive.
5.2.5.3.6.6   Application Timing (Site Status) code cannot be a code restricted in Product Level or Site Level.

Xml Code Snippet:
```
<title>Scenario Attributes</title>
<subject2>
   <substanceAdministration>

      <!-- other elements -->

      <!-- (1..*) Application Timing (Site Status) -->
      <subjectOf>
         <characteristic>

            <code code="1005020" codeSystem="2.16.840.1.113883.6.275.1"
                  displayName="Application Timing (Site Status)"/>

            <value xsi:type="SXCM_CD" operator="I"
               code="{Application Timing (Site Status)}"
               codeSystem="2.16.840.1.113883.6.275.1"
               displayName="{Application Timing (Site Status)
DisplayName}"/>
         </characteristic>
      </subjectOf>
```

5.2.5.3.7 *Application Timing (Day)* (+)

Identifies when pesticide application occurs in relation to the time of day (For example After Sunrise, Evening, After Dark, etc.). This information is not required. Only enter this information if it is explicitly stated on the label.

Entry type: *"Application Timing (Time of Day)"* picklist selection.

Validation Procedures:
5.2.5.3.7.1   There is zero to many Application Timing (Time of Day) characteristics.
5.2.5.3.7.2   Application Timing (Time of Day) code is from the list *Application Timing (Time of Day)*.
5.2.5.3.7.3   Display name matches the code.
5.2.5.3.7.4   The value xsi:type is "SXCM_CD" meaning a set of codes.
5.2.5.3.7.5   The operator attribute is "I" meaning inclusive.
5.2.5.3.7.6   Application Timing (Time of Day) code cannot be a code restricted in Product Level or Site Level.

Xml Code Snippet:
```
<title>Scenario Attributes</title>
<subject2>
   <substanceAdministration>
```

```
        <!-- other elements -->

        <!-- (0..*) Application Timing (Time of Day) -->
        <subjectOf>
           <characteristic>

              <code code="1004960" codeSystem="2.16.840.1.113883.6.275.1"
                    displayName="Application Timing (Time of Day)"/>

              <value xsi:type="SXCM_CD" operator="I"
                    code="{Application Timing (Time of Day)}"
                    codeSystem="2.16.840.1.113883.6.275.1"
                    displayName="{Application Timing (Time of Day)
DisplayName}"/>
           </characteristic>
        </subjectOf>
```

5.2.5.3.8 *Application Timing (Pest)* (+)

Identifies when a pesticide application in relation to the targeted pest (For example After Weed Emergence, When Pests Occur, When damage from pest is observed, etc.). This is required if the site timing "All crop/site stages possible (e.g., timing determined solely by pest pressure)" was entered for Application Timing (Site), otherwise the information is not required and should only be entered if it is explicitly stated on the label.

Entry type: *"Application Timing (Timing of Pest)"* picklist selection.

Validation Procedures:

5.2.5.3.8.1	There is zero to many Application Timing (Pest) characteristics.
5.2.5.3.8.2	Application Timing (Timing of Pest) code is required if "All crop stages possible (e.g., timing determined solely by pest pressure)" is selected for Application Timing (Site Status).
5.2.5.3.8.3	Application Timing (Timing of Pest) code is from the list *Application Timing (Timing of Pest)*.
5.2.5.3.8.4	Display name matches the code.
5.2.5.3.8.5	The value xsi:type is "SXCM_CD" meaning a set of codes.
5.2.5.3.8.6	The operator attribute is "I" meaning inclusive.
5.2.5.3.8.7	Application Timing (Timing of Pest) code cannot be a code restricted in Product Level or Site Level.

Xml Code Snippet:

```
<title>Scenario Attributes</title>
<subject2>
   <substanceAdministration>

      <!-- other elements -->

      <!-- (0..*) Application Timing (Pest) -->
      <subjectOf>
         <characteristic>

            <code code="1004921" codeSystem="2.16.840.1.113883.6.275.1"
                  displayName="Application Timing (Timing of Pest)"/>
```

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```
            <value xsi:type="SXCM_CD" operator="I"
                code="{Application Timing (Timing of Pest)}"
                codeSystem="2.16.840.1.113883.6.275.1"
                displayName="{Application Timing (Timing of Pest)
DisplayName}"/>
          </characteristic>
        </subjectOf>
```

5.2.5.4   Use Scenario Level Restrictions/Limitations

Identifies only Scenario Level Restrictions/Limitations. Restrictions/Limitations are
entered at this level if they differer between scenarios. Information for the same
Restriction/Limitation cannot be entered at multiple levels. Restrictions/Limitations
should only be recorded in the Use Index if the label explicitly restricts or limits the
identified data element in legally enforceable language. Statements that include terms like
"should" or "for best results" are not legally enforceable, and should not be recorded.

Multiple entries are possible for many Restrictions/Limitations. In this document, data
elements that may have multiple entries are marked with a (+) after their title.
Additionally, the validation rules for each element indicate if entry is optional and the
number of entries that can be entered.

Leaving a restriction blank indicates that there is no restriction at this level.

Validation Procedures:

5.2.5.4.1.1   There is one "Use Scenario Level Restrictions/Limitations" section
            per "Scenario Level section".
5.2.5.4.1.2   The section title is the same as the section code displayName.
5.2.5.4.1.3   The section link is optional.
5.2.5.4.1.4   If the section link is provided then the section link is a unique string
            within the document.
5.2.5.4.1.5   The section id is a unique UUID within the document.

Xml Code Snippet:

```
<component>
   <section ID="{Section Link}">
      <id root="{Section Id}"/>
      <code code="3810094" codeSystem="2.16.840.1.113883.6.275.1"
            displayName="Use Scenario Level Restrictions/Limitations"/>
      <title>Use Scenario Level Restrictions/Limitations</title>
```

5.2.5.4.2 *Geographic Area Allowed* (+)

Identifies restrictions associated with geographic location, at the state and county level, by listing areas where application *is* allowed. This is a required field at either the Product, Site, or Scenario level for each method. If applications are not restricted to any particular geographic area, select "United States". If application is not allowed in a particular area, select all areas except the prohibited area.

> **Entry type:** "*Geographic Area*" picklist selection.

> **Validation Procedures:**
> 5.2.5.4.2.1 There is at least one Geographic Area for each scenario. The scenario is considered to have Geographic Area if it is provided at the Product, Site, or Scenario levels.
> 5.2.5.4.2.2 If Geographic Area is provided at the Product or site level, there should be no Geographic Area provided at any scenario level.
> 5.2.5.4.2.3 Code is from the list "*Geographic Area*".
> 5.2.5.4.2.4 DisplayName matches the code.

> **Xml Code Snippet:**

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (1..*) Geographic Area Allowed -->
            <component>
               <requirement>
                  <code code="1005202"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Geographic Area">
                     <qualifier xsi:type="CR">
                        <value code="{Geographic Area Code}"
                                codeSystem="2.16.840.1.113883.6.275.1"
                                displayName="{Geographic Area
DisplayName}"/>
                     </qualifier>
                  </code>
               </requirement>
            </component>
```

5.2.5.4.3 *Food Site Relationship*

Identifies if application(s) are intended to come in contact with food or feed, which may result in the need for a tolerance. This information is required for agricultural crops (at either the Product, Site, or Scenario level for each method) to establish whether crops may be used as food or feed (Bearing), or may not be used as food or feed (Non-Bearing/Dormant, Grown for Seed) If the product labeling for non-agricultural sites explicitly prohibits applications that may contact food or feed, No Food/Feed Contact should be selected (see definitions for further guidance).

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Entry type: "*Use Site Food Relationship*" picklist selection.

Validation Procedures:

5.2.5.4.3.1   There is one Food Site Relationship for each scenario. The Scenario is considered to have a Food Site Relationship if it is provided at the Product, Site, or Scenario Levels.

5.2.5.4.3.2   If Food Site Relationship is provided at the Product or Site Level (for the Scenario in question), there should be no Geographic Area provided at the Scenario level.

5.2.5.4.3.3   Code is from the list *Use Site Food Relationship*.

5.2.5.4.3.4   DisplayName matches the code.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

          <!-- other elements -->

           <!-- (1..1) Food Site Relationship -->
           <component>
              <requirement>
                 <code code="1005021"
codeSystem="2.16.840.1.113883.6.275.1"
                       displayName="Use Site Food Relationship">
                    <qualifier xsi:type="CR">
                       <value code="{Use Site Food Relationship Code}"
                              codeSystem="2.16.840.1.113883.6.275.1"
                              displayName="{Use Site Food Relationship
DisplayName}"/>
                    </qualifier>
                 </code>
              </requirement>
           </component>
```

5.2.5.4.4 Restriction Maximum Active Ingredient Rate Across Products

Identifies the maximum amount of active ingredient (or in some cases the maximum amount of a chemical class) that may be applied to a given area across products that contain the same active ingredient (or a.i. class). This restriction is often stated on labels as "Do not apply more than [x amount] of product per [year or crop cycle] from this or any other product containing this active ingredient".

Entry type: value unit, per value unit, per "*Application Rate Measurement Period"* picklist selection.

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Validation Procedures:

5.2.5.4.4.1   There are zero or one Restriction Maximum Active Ingredient Rate Across Products substanceAdministrations.

5.2.5.4.4.2   If Maximum Active Ingredient Rate Across Products substanceAdministrations is provided at the Product or Site, then there should not also be a Maximum Active Ingredient Rate Across Products substance Administrations provided at the Scenario level.

5.2.5.4.4.3   The Maximum Rate is a number.

5.2.5.4.4.4   Numerator units must be one of the following:

- Standard Weight / Mass
- Standard Volume / Capacity
- Miscellaneous Application Unit
- Concentration
- Non-Standard Volume / Capacity

5.2.5.4.4.5   Denominator units must be one of the following:

- Standard Area
- Standard Length
- Standard Weight / Mass
- Standard Volume / Capacity
- Time
- Blank (if numerator is Concentration)
- Non-Standard Volume / Capacity
- Non-standard - Target (with acreage rate limit)
- Non-Standard Weight / Mass
- Miscellaneous – Target

5.2.5.4.4.6   Method code is from the list *Application Rate Measurement Period*.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Restriction Max A.I. Rate Across Products -->
            <component>
              <substanceAdministration>
                <subjectOf>
                  <characteristic>
                    <code code="1005323"
                          codeSystem="2.16.840.1.113883.6.275.1"
                          displayName="Max A.I. Rate Across Products"/>
                    <value xsi:type="RTO_PQ_PQ">
                      <numerator xsi:type="PQ" nullFlavor="OTH">
                        <translation value="{Maximum Rate}"
                               displayName="{Unit DisplayName"
                               code="{Unit Code}"
                               codeSystem="2.16.840.1.113883.6.275.1"/>
```

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```
                            </numerator>
                            <denominator xsi:type="PQ" nullFlavor="OTH">
                              <translation value="{Per Quantity}"
                                    displayName="{Unit DisplayName"
                                    code="{Unit Code}"
                                    codeSystem="2.16.840.1.113883.6.275.1"/>
                            </denominator>
                          </value>
                          <methodCode code="{Method Code}"
                                codeSystem="2.16.840.1.113883.6.275.1"
                                displayName="{Method DisplayName}"/>
                        </characteristic>
                      </subjectOf>
                    </substanceAdministration>
                  </component>
```

5.2.5.4.5 *Rotational Crop*

Identifies if any rotational crop restrictions apply to this specific product. This is a
presence/absence indicator. If any restrictions to rotation plantings appear on the label
(including what may be planted following the current crop, or the length of time that must
pass before a crop can be planted in the area), then Rotational Crop should be selected.

Entry type: presence/absence selection (absence selected as default).

Validation Procedures:
5.2.5.4.5.1   There is zero to one Rotational Crop requirements.
5.2.5.4.5.2   If Rotational Crop is provided at the Product or Site level, then there
              should not also be Rotational Crop provided at the Scenario level.

Xml Code Snippet:
```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Rotational Crop -->
            <component>
               <requirement>
                  <code code="1005337"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Rotational Crop"/>
               </requirement>
            </component>
```

5.2.5.4.6 *Applicator Class Restrictions* (+)

Identifies those individuals or groups of individuals who are allowed to apply the
product, if only certain classes of applicator are allowed. The existence of an Application

Class requirement(s), by definition, indicates all other applicators are restricted from using the product.

Entry type: "*Applicator Class Restrictions*" picklist selection.

Validation Procedures:

5.2.5.4.6.1 Code is from the list *Applicator Class Restrictions*.
5.2.5.4.6.2 DisplayName matches the code.
5.2.5.4.6.3 There is zero to many Applicator Class Restrictions.
5.2.5.4.6.4 If Applicator Class Restriction(s) is/are provided at the Product or Site level, then it should not also be provided at the Scenario level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Applicator Class Restrictions -->
            <component>
               <requirement>
                  <code code="1004442"
codeSystem="2.16.840.1.113883.6.275.1"
                          displayName="Applicator Class Restrictions">
                     <qualifier xsi:type="CR">
                        <value code="{Applicator Class Restriction}"
                                 codeSystem="2.16.840.1.113883.6.275.1"
                                 displayName="{Applicator Class
Restriction DisplayName}"/>
                     </qualifier>
                  </code>
               </requirement>
            </component>
```

5.2.5.4.7 *Personal Protection Equipment (PPE) / Engineering Control* (+)

This indicates the PPE and/or engineering controls are required on for use of the product. Information captured here is not limited to information in the Agricultural Use box on the label. It is intended to capture requirements for PPE/Engineering Controls that appear anywhere on the label.

Entry type: "*Personal Protection Equipment (PPE)/Engineering Control*" picklist selection.

Validation Procedures:

5.2.5.4.7.1 There is zero to many PPE/Engineering Control requirements.
5.2.5.4.7.2 If PPE/Engineering Control(s) is/are provided at the Site or Scenario Level, then it should not also be provided at the Product level.

5.2.5.4.7.3   Code is from the list *Personal Protection Equipment (PPE)/Engineering Control*.
5.2.5.4.7.4   DisplayName matches the code.
5.2.5.4.7.5   If Personal Protection Equipment (PPE) / Engineering Control is/are provided at the Product or Site level, then there should not also be Personal Protection Equipment (PPE) / Engineering Control provided at the Scenario level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) PPE/Engineering control -->
            <component>
               <requirement>
                  <code code="1005024"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="PPE/Engineering Control">
                     <qualifier xsi:type="CR">
                        <value code="{PPE/Engineering Control Code}"
                               codeSystem="2.16.840.1.113883.6.275.1"
                               displayName="{PPE/Engineering Control
DisplayName}"/>
                     </qualifier>
                  </code>
               </requirement>
            </component>
```

5.2.5.4.8 *Restricted Entry Interval (REI)*

Identifies the minimum period of time after a pesticide application when entry into the treated area is restricted. Includes WPS and non-WPS re-entry intervals.

Entry type: value unit

Validation Procedures:
5.2.5.4.8.1   There is zero to one Restricted Entry Interval requirements.
5.2.5.4.8.2   The value of sequenceNumber must be 3.
5.2.5.4.8.3   The Period of Time is a number.
5.2.5.4.8.4   Units must be time units.
5.2.5.4.8.5   If Restricted Entry Interval (REI) is provided at the Site or Scenario Level, then it should not also be provided at the Product level

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) REI -->
            <component>
               <!-- after application -->
               <sequenceNumber value="3"/>

               <requirement>
                  <code code="1005325"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Minimum period of time before worker
re-entry"/>
                  <effectiveTime xsi:type="IVL_TS">
                    <width xsi:type="PQ" nullFlavor="OTH">
                      <translation value="{Period of time value}"
                              displayName="{Unit DisplayName}"
                              code="{Unit Code}"
                              codeSystem="2.16.840.1.113883.6.275.1"/>
                    </width>
                  </effectiveTime>
               </requirement>
            </component>
```

5.2.5.4.9 Minimum Retreatment Interval (MRI)

Identifies the minimum period of time after an application that must pass before the
product can be reapplied to the same area or target.

Entry type: value unit

Validation Procedures:

5.2.5.4.9.1 There is zero to one Minimum Retreatment Interval requirements.
5.2.5.4.9.2 The value of sequenceNumber must be 3.
5.2.5.4.9.3 The Minimum Retreatment Interval is a number.
5.2.5.4.9.4 Units must be time units.
5.2.5.4.9.5 Required if more than one application is allowed, or if the single rate
            is not equal to the crop cycle/yearly rate.
5.2.5.4.9.6 If Minimum Retreatment Interval (MRI) is provided at the Product
            or Site level, then there should not also be Minimum Retreatment
            Interval (MRI) provided at the Scenario level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>
```

```
            <!-- other elements -->

             <!-- (0..1) MRI -->
             <component>
                <!-- after application -->
                <sequenceNumber value="3"/>

                <requirement>
                   <code code="1005326"
                         codeSystem="2.16.840.1.113883.6.275.1"
                         displayName="Minimum period of time before re-
application"/>

                    <effectiveTime xsi:type="IVL_TS">
                      <width xsi:type="PQ" nullFlavor="OTH">
                        <translation value="{Minimum period of time}"
                                displayName="{Unit DisplayName}"
                                code="{Unit Code}"
                                codeSystem="2.16.840.1.113883.6.275.1"/>
                      </width>
                    </effectiveTime>
                 </requirement>
             </component>
```

5.2.5.4.10   Pre-Harvest Interval (PHI) (+)

Identifies the minimum period of time that must pass after an application before
crop/commodity. This data element may be blank if the final application is restricted to
occur at or before a crop growth stage that is typically 30 days or more before harvest.

Entry type: "*Pre-Harvest Interval (PHI) Category*" picklist selection, and value
unit.

Validation Procedures:

5.2.5.4.10.1 There is zero to many Pre-Harvest Interval requirements.
5.2.5.4.10.2 The sequenceNumber value is 3.
5.2.5.4.10.3 Code is from the list *Pre-Harvest Interval (PHI) Category*.
5.2.5.4.10.4 DisplayName matches the code.
5.2.5.4.10.5 The Pre-Harvest interval is a number.
5.2.5.4.10.6 Units must be time units.
5.2.5.4.10.7 If Pre-Harvest Interval (PHI) is provided at the Product or Site level,
              then there should not also be Pre-Harvest Interval (PHI) provided at
              the Scenario level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->
```

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```
                     <!-- (0..*) PHI -->
                     <component>
                        <!-- after application -->
                        <sequenceNumber value="3"/>

                        <requirement>
                           <code code="1005028"
codeSystem="2.16.840.1.113883.6.275.1"
                                 displayName="PHI Category">
                              <qualifier xsi:type="CR">
                                 <value code="{PHI Category Code}"
                                        codeSystem="2.16.840.1.113883.6.275.1"
                                        displayName="{PHI Category
DisplayName}"/>
                              </qualifier>
                           </code>

                           <effectiveTime xsi:type="IVL_TS">
                             <width xsi:type="PQ" nullFlavor="OTH">
                              <translation value="{PHI Value}"
                                        code="{Unit Code}"
                                        codeSystem="2.16.840.1.113883.6.275.1"
                                        displayName="{Unit DisplayName}"/>
                             </width>
                           </effectiveTime>
                        </requirement>

                     </component>
```

5.2.5.4.11 *Pre-Grazing Interval (PGI)/Pre-Feeding Interval (PFI)* (+)

Identifies the minimum period of time that must pass after an application before an
identified group of animals may graze in treated areas, or may be fed treated material.

Entry type: "*Pre-Grazing Interval (PGI)/ Pre-Feeding Interval Category*"
picklist selection, and value unit.

Validation Procedures:

5.2.5.4.11.1 There is zero to many Pre-Grazing Intervals requirements.
5.2.5.4.11.2 The sequenceNumber value is 3.
5.2.5.4.11.3 Code is from the list *Pre-Grazing Interval (PGI)/ Pre-Feeding
              Interval Category*.
5.2.5.4.11.4 DisplayName matches the code.
5.2.5.4.11.5 The Pre-Grazing interval is a number.
5.2.5.4.11.6 Units must be time units.
5.2.5.4.11.7 If Pre-Grazing Interval (PGI)/ Pre-Feeding Interval is/are provided at
              the Product or Site level, then there should not also be Pre-Grazing
              Interval (PGI)/ Pre-Feeding Interval provided at the Scenario level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>
```

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```
            <!-- other elements -->

            <!-- (0..*) PGI -->
            <component>

                <!-- after application -->
                <sequenceNumber value="3"/>

                <requirement>
                    <code code="1005026"
codeSystem="2.16.840.1.113883.6.275.1"
                          displayName="PGI Category">
                        <qualifier xsi:type="CR">
                            <value code="{PGI Category Code}"
                                   codeSystem="2.16.840.1.113883.6.275.1"
                                   displayName="{PGI Category
DisplayName}"/>
                        </qualifier>
                    </code>

                    <effectiveTime xsi:type="IVL_TS">
                        <width xsi:type="PQ" nullFlavor="OTH">
                            <translation value="{Pre-Grazing Interval}"
                                         code="{Unit Code}"
                                         codeSystem="2.16.840.1.113883.6.275.1"
                                         displayName="{Unit DisplayName}"/>
                        </width>
                    </effectiveTime>
                </requirement>
            </component>
```

5.2.5.4.12   *Pre-Slaughter Interval (PSI)* (+)

Identifies the minimum period of time after an application that must pass before an identified group of animals that have contacted the product can be slaughtered for food or feed.

> **Entry type:** "*Pre-Slaughter Interval (PSI) Category*" picklist selection, and value unit.

> **Validation Procedures:**
> 5.2.5.4.12.1 There is zero to many Pre-Slaughter Interval requirements.
> 5.2.5.4.12.2 The sequenceNumber value is 3.
> 5.2.5.4.12.3 Code is from the list *Pre-Slaughter Interval (PSI) Category*.
> 5.2.5.4.12.4 DisplayName matches the code.
> 5.2.5.4.12.5 Pre-Slaughter interval is a number.
> 5.2.5.4.12.6 Units must be time units.
> 5.2.5.4.12.7 If Pre-Slaughter Interval (PSI) is/are provided at the Product or Site level, then there should not also be Pre-Slaughter Interval (PSI) provided at the Scenario level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) PSI -->
            <component>
               <!-- after application -->
               <sequenceNumber value="3"/>

               <requirement>
                  <code code="1005027"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="PSI Category">
                     <qualifier xsi:type="CR">
                        <value code="{PSI Category Code}"
                               codeSystem="2.16.840.1.113883.6.275.1"
                               displayName="{PSI Category
DisplayName}"/>
                     </qualifier>
                  </code>

                  <effectiveTime xsi:type="IVL_TS">
                    <width xsi:type="PQ" nullFlavor="OTH">
                      <translation value="{Pre-Slaughter Interval}"
                               code="{Unit Code}"
                               codeSystem="2.16.840.1.113883.6.275.1"
                               displayName="{Unit DisplayName}"/>
                    </width>
                  </effectiveTime>
               </requirement>
            </component>
```

5.2.5.4.13   *Buffer Zone* (+)

Identifies the minimum distance that is required between the area where a product is
applied and the specific area to be protected from the pesticide application.

Entry type: "*Buffered Area*" picklist selection, and value unit.

Validation Procedures:

5.2.5.4.13.1 There is zero to many Buffer Area preconditions.
5.2.5.4.13.2 The checkPoint code is 'T'.
5.2.5.4.13.3 Code is from the list *Buffered Area*.
5.2.5.4.13.4 DisplayName matches the code.
5.2.5.4.13.5 The Buffered Area value is a number.
5.2.5.4.13.6 Units must be Standard Length units.
5.2.5.4.13.7 If Buffered Area is provided at the Product or Site level, then there
should not also be Buffered Area provided at the Scenario level.

```xml
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Buffer Zone -->
            <precondition>
               <!-- observation must hold true throughout application -->
               <checkpointCode code="T"/>

                <observationCriterion>
                   <code code="1004980"
codeSystem="2.16.840.1.113883.6.275.1"
                         displayName="Buffered Area">
                      <qualifier xsi:type="CR">
                         <value code="{Buffered Area Code}"
                                 codeSystem="2.16.840.1.113883.6.275.1"
                                 displayName="{Buffered Area
DisplayName}" />
                      </qualifier>
                   </code>

                   <value xsi:type="PQ" nullFlavor="OTH">
                     <translation value="{Buffered Area value}"
                           displayName="{Unit DisplayName}"
                           code="{Unit Code}"
                           codeSystem="2.16.840.1.113883.6.275.1"/>
                   </value>

                </observationCriterion>
            </precondition>
```

5.2.5.4.14   Max Release Height

Identifies the maximum distance between the point of release from the application equipment and the top of crop or ground.

Entry type: value unit.

Validation Procedures:

5.2.5.4.14.1 There is zero to one Maximum Release Height precondition.
5.2.5.4.14.2 The checkPoint code is 'T'.
5.2.5.4.14.3 The Release Height is a number.
5.2.5.4.14.4 Units must be Standard Length units.
5.2.5.4.14.5 If Maximum Release Height is provided at the Product or Site level, then there should not also be Maximum Release Height provided at the Scenario level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Max Release Height -->
            <precondition>
               <!-- observation must hold true throughout application -->
               <checkpointCode code="T"/>

               <observationCriterion>
                  <code code="1005327"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Release Height"/>

                  <value xsi:type="PQ" nullFlavor="OTH">
                    <translation value="{Release Height}"
                            displayName="{Unit DisplayName}"
                            code="{Unit Code}"
                            codeSystem="2.16.840.1.113883.6.275.1"/>
                  </value>

               </observationCriterion>
            </precondition>
```

5.2.5.4.15   *Max Wind Speed*

Identifies the maximum wind speed allowed during application.

Entry type: value unit.

Validation Procedures:

5.2.5.4.15.1 There is zero to one Maximum Wind Speed precondition.
5.2.5.4.15.2 The checkPoint code is 'T'.
5.2.5.4.15.3 The Windspeed is a number.
5.2.5.4.15.4 Units must be speed units.
5.2.5.4.15.5 If Maximum Wind Speed is provided at the Product or Site level,
              then there should not also be Maximum Wind Speed provided at the
              Scenario level.

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Xml Code Snippet:

```xml
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Max Wind Speed -->
            <precondition>
               <!-- observation must hold true throughout application -->
               <checkpointCode code="T"/>

               <observationCriterion>

                  <code code="1005328"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Windspeed"/>

                  <value xsi:type="PQ" nullFlavor="OTH">
                    <translation value="{Wind Speed}"
                          displayName="{Unit DisplayName}"
                          code="{Unit Code}"
                          codeSystem="2.16.840.1.113883.6.275.1"/>
                  </value>

               </observationCriterion>
            </precondition>
```

5.2.5.4.16   Temperature Range at Application

Identifies the minimum and maximum temperatures at which application(s) may be made.

Entry type: value unit, value unit.

Validation Procedures:

5.2.5.4.16.1 There is zero to one Temperature at Application preconditions.
5.2.5.4.16.2 The checkPoint code is 'B'.
5.2.5.4.16.3 The Minimum Temperature is a number.
5.2.5.4.16.4 The Maximum Temperature is a number.
5.2.5.4.16.5 The Minimum and Maximum Temperature units must be Temperature Units.
5.2.5.4.16.6 If Minimum and/or Maximum Temperatures is/are provided at the Product or Site level, then there should not also be Minimum and/or Maximum Temperatures provided at the Scenario level.

Xml Code Snippet:

```xml
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>
```

```
            <!-- other elements -->

            <!-- (0..1) Temperature Range at Application -->
            <precondition>
               <!-- observation checked before application -->
               <checkpointCode code="B"/>

               <observationCriterion>
                  <code code="1005330"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Temperature Range at Application"/>

                  <value xsi:type="IVL_PQ">
                    <low xsi:type="IVXB_PQ" nullFlavor="OTH">
                      <translation value="{Minimum Temperature}"
                            displayName="{Unit DisplayName}"
                            code="{Unit Code}"
                            codeSystem="2.16.840.1.113883.6.275.1"/>
                    </low>
                    <high xsi:type="IVXB_PQ" nullFlavor="OTH">
                      <translation value="{Maximum Temperature}"
                            displayName="{Unit DisplayName}"
                            code="{Unit Code}"
                            codeSystem="2.16.840.1.113883.6.275.1"/>
                    </high>
                  </value>
               </observationCriterion>
            </precondition>
```

5.2.5.4.17   *ASABE Droplet Size* (+)

Identifies restrictions associated with the application droplet size according to the
ASABE 572 standard. Droplet sizes that are acceptable for application should be
selected. This is required for broadcast applications using aerial or ground equipment.

Entry type: "*ASABE Droplet Size*" picklist selection, and value unit.

Validation Procedures:

5.2.5.4.17.1 There is zero to many ASABE requirements.
5.2.5.4.17.2 Required for Type = 'broadcast', Form as Applied = 'liquid
              formations' and Application Equipment = 'Aerial' or 'Groundboom'.
5.2.5.4.17.3 Code is from the list *ASABE Droplet Size*.
5.2.5.4.17.4 DisplayName matches the code.
5.2.5.4.17.5 If ASABE Droplet Size is/are provided at the Product or Site level,
              then there should not also be ASABE Droplet Size provided at the
              Scenario level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->
```

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```
                <!-- (0..*) ASABE Droplet Size -->
                <component>
                   <requirement>
                      <code code="1004962"
codeSystem="2.16.840.1.113883.6.275.1"
                            displayName="ASABE Droplet Size">
                         <qualifier xsi:type="CR">
                            <value code="{ASABE Droplet Size Code}"
                                   codeSystem="2.16.840.1.113883.6.275.1"
                                   displayName="{ASABE Droplet Size
DisplayName}"/>
                         </qualifier>
                      </code>
                   </requirement>
                </component>
```

5.2.5.4.18   *Soil Incorporation Depth and Time*

Identifies the minimum soil incorporation depth that is required for the application, and
the maximum amount of time that may pass before incorporation takes place. If the
incorporation is done during application, enter the time as "0" minutes.

Entry type: value unit, value unit.

Validation Procedures:

5.2.5.4.18.1 There is zero to one Soil Incorporation Depth and Time
              observations.
5.2.5.4.18.2 The sequenceNumber value is 3.
5.2.5.4.18.3 The Maximum time after application is a number.
5.2.5.4.18.4 The Maximum time unit is a time unit.
5.2.5.4.18.5 The Minimum depth is a number.
5.2.5.4.18.6 The Minimum depth unit is a Standard Length units.
5.2.5.4.18.7 If Soil Incorporation Depth and Time are provided at the Product or
              Site level, then there should not also be Soil Incorporation Depth and
              Time provided at the Scenario level.

Xml Code Snippet:
```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Soil Incorporation Min Depth -->
            <component>
               <!-- after application -->
               <sequenceNumber value="3"/>

               <!-- wait some period of time -->
               <pauseQuantity xsi:type="PQ" nullFlavor="OTH">
```

```
                    <translation value="{Maximum time after application}"
                            displayName="{Unit DisplayName}"
                            code="{Unit Code}"
                            codeSystem="2.16.840.1.113883.6.275.1"/>
                </pauseQuantity>

                <!-- conduct observation -->
                <monitoringObservation>
                    <code code="1005331"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Soil Incorporation Depth and Time"/>

                    <precondition>
                        <observationCriterion>
                            <!-- Soil Incorporation Min Depth -->
                            <code code="1005332"
                                codeSystem="2.16.840.1.113883.6.275.1"
                                displayName="Soil Incorporation Min
Depth"/>

                            <value xsi:type="IVL_PQ">
                              <low xsi:type="IVXB_PQ" nullFlavor="OTH">
                                <translation code="{Unit Code}"
                                    codeSystem="2.16.840.1.113883.6.275.1"
                                    displayName="{Unit DisplayName"
                                    value="{Minimum Depth}"/>
                              </low>
                            </value>
                        </observationCriterion>
                    </precondition>
                </monitoringObservation>
            </component>
```

5.2.5.4.19   Restricted Soil Type (+)

Identifies any soil type(s) to which the product cannot be applied using these methods.

Entry type: "*Soil Type*" picklist selection, and value unit.

Validation Procedures:

5.2.5.4.19.1 There is zero to many Restricted Soil Type preconditions.

5.2.5.4.19.2 The checkPoint code is 'B'.

5.2.5.4.19.3 Code is from the list *Soil Type*.

5.2.5.4.19.4 DisplayName matches the code.

5.2.5.4.19.5 If Restricted Soil Type is provided at the Product or Site level, then there should not also be Restricted Soil Type provided at the Scenario level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
    <substanceAdministration>
        <componentOf>
            <protocol>

                <!-- other elements -->
```

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```
                 <!-- (0..*) Restricted Soil Type -->
                 <precondition>
                   <!-- observation checked before application -->
                   <checkpointCode code="B"/>

                   <observationCriterion>

                     <code code="1004961"
                           codeSystem="2.16.840.1.113883.6.275.1"
                           displayName="Soil Type"/>

                     <value xsi:type="CD" code="{Restricted Soil Type}"
                            codeSystem="2.16.840.1.113883.6.275.1"
                            displayName="{Restricted Soil Type DisplayName}"
/>

                     <!-- not the condition -->
                     <valueNegationInd value="true"/>

                   </observationCriterion>
                 </precondition>
```

5.2.5.4.20   Minimum Percent Soil Organic Matter

Identifies the minimum percent soil organic matter to which application(s) may be made.

Entry type: value unit.

Validation Procedures:

5.2.5.4.20.1 There is zero to one Minimum Percent Soil Organic Matter precondition.

5.2.5.4.20.2 The checkPoint code is 'B'.

5.2.5.4.20.3 The Percent Soil value is a number.

5.2.5.4.20.4 The units are Percent (code "3627136") with displayName "%".

5.2.5.4.20.5 If Minimum Percent Soil Organic Matter is provided at the Product or Site level, then there should not also be Minimum Percent Soil Organic Matter provided at the Scenario level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Minimum Percent Soil Organic Matter -->
            <precondition>

               <!-- observation checked before application -->
               <checkpointCode code="B"/>

               <observationCriterion>
```

```
                         <code code="1005333"
codeSystem="2.16.840.1.113883.6.275.1"
                               displayName="Percent Soil Organic Matter"/>

                    <value xsi:type="PQ" nullFlavor="OTH">
                      <translation code="3627136"
                               codeSystem="2.16.840.1.113883.6.275.1"
                               displayName="%"
                               value="{Percent Soil Organic Matter}"/>
                    </value>

               </observationCriterion>
            </precondition>
```

5.2.5.4.21   *Minimum Age of Animal to be Treated*

Identifies the minimum age of animals to which application(s) may be made.

Entry type: value unit.

Validation Procedures:

5.2.5.4.21.1 There is zero to one Minimum Age preconditions.
5.2.5.4.21.2 The checkPoint code is 'B'.
5.2.5.4.21.3 The Minimum Age is a number.
5.2.5.4.21.4 Minimum Age units must be time units.
5.2.5.4.21.5 If Minimum Age of Animal to be Treated provided at the Product or
              Site level, then there should not also be Minimum Age of Animal to
              be Treated provided at the Scenario level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Minimum Age of Animal to be treated -->
            <precondition>
               <!-- observation checked before application -->
               <checkpointCode code="B"/>

               <observationCriterion>
                 <code code="1005334"
                       codeSystem="2.16.840.1.113883.6.275.1"
                       displayName="Minimum Age of Animal to be
treated"/>
                 <value xsi:type="PQ" nullFlavor="OTH">
                   <translation value="{Minimum Age}"
                            displayName="{Units DisplayName}"
                            code="{Minimum Age units}"
                            codeSystem="2.16.840.1.113883.6.275.1"/>
                 </value>
               </observationCriterion>
            </precondition>
```

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5.2.5.4.22   *Minimum Weight of Animal to be treated*

Identifies the minimum weight of animals to which application(s) may be made.

> **Entry type:** value unit.

> **Validation Procedures:**

5.2.5.4.22.1 There is zero to one Minimum Weight preconditions.
5.2.5.4.22.2 The checkPoint code is 'B'.
5.2.5.4.22.3 The Minimum Weight is a number.
5.2.5.4.22.4 The Minimum Weight units must be Standard Weight/Capacity units.
5.2.5.4.22.5 If Minimum Weight of Animal to be Treated is provided at the Product or Site level, then there should not also be Minimum Weight of Animal to be Treated provided at the Scenario level.

> **Xml Code Snippet:**

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..1) Minimum Weight of Animal to be treated -->
            <precondition>
               <!-- observation checked before application -->
               <checkpointCode code="B"/>

               <observationCriterion>
                  <code code="1005335 "
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Minimum Weight of Animal"/>

                 <value xsi:type="PQ" nullFlavor="OTH">
                   <translation value="{Minimum Weight}"
                            displayName="{Units DisplayName}"
                            code="{Minimum Age units}"
                            codeSystem="2.16.840.1.113883.6.275.1"/>
                 </value>
               </observationCriterion>
            </precondition>
```

5.2.5.4.23   *Pollinator* (+)

Identifies specific label restrictions to application based on pollinator protection. The statements selected from the picklist and those that appear on the label must not be identical, but must have the same general meaning.

> **Entry type:** "*Pollinator Protection Statements*" picklist selection.

Validation Procedures:

5.2.5.4.23.1 There is zero to many Pollinator Protection Statement requirements.

5.2.5.4.23.2 Code is from the list *Pollinator Protection Statements*.

5.2.5.4.23.3 DisplayName matches the code.

5.2.5.4.23.4 If Pollinator Protection Statements is/are provided at the Product or Site level, then there should not also be Pollinator Protection Statements provided at the Scenario level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Pollinator -->
            <component>
               <requirement>
                  <code code="1005022"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Pollinator Protect Statements">
                     <qualifier xsi:type="CR">
                        <value code="{Pollinator Code}"
                                 codeSystem="2.16.840.1.113883.6.275.1"
                                 displayName="{Pollinator DisplayName}"/>
                     </qualifier>
                  </code>
               </requirement>
            </component>
```

5.2.5.4.24   Bulletins Live

Identifies if there is an Endangered Species County Level Bulletin indicator on the label. This is a presence/absence indicator. If a bulletins live statement appears on the label, then Bulletins Live should be selected.

Entry type: presence/absence selection.

Validation Procedures:

5.2.5.4.24.1 There is zero to one Bulletins Live requirements.

5.2.5.4.24.2 If Bulletins Live restriction is provided at the Product or Site level, then there should not also be Bulletins Live restriction provided at the Scenario level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>
```

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```
            <!-- other elements -->

            <!-- (0..1) Bulletins Live -->
            <component>
               <requirement>
                  <code code="1005336"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Bulletins Live"/>
               </requirement>
            </component>
```

5.2.5.4.25   *Applications to Water* (+)

Identifies specific label a restrictions related to the treatment of a volume of water
(includes flooded field applications and waterbodies). The statements selected from the
picklist and those that appear on the label must not be identical, but must have the same
general meaning.

Entry type: "*Water Protection Statements*" picklist selection.

Validation Procedures:

5.2.5.4.25.1 There is zero to many Applications to Water requirements.
5.2.5.4.25.2 Code is from the list *Water Protection Statements*.
5.2.5.4.25.3 DisplayName matches the code.
5.2.5.4.25.4 If Water Protection Statements is/are provided at the Product or Site
              level, then there should not also be Water Protection Statements
              provided at the Scenario level.

Xml Code Snippet:
```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- (0..*) Applications to Water -->
            <component>
                        <requirement>
                  <code code="1005023"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Water Protection Statement">
                     <qualifier xsi:type="CR">
                        <value code="{Water Protection Statement Code}"
                                codeSystem="2.16.840.1.113883.6.275.1"
                                displayName="{Water Protection Statement
DisplayName}"/>
                     </qualifier>
                  </code>
               </requirement>
            </component>
```

5.2.5.4.26   *Secondary Manufacturing*

Identifies if there are any restrictions which limit further manufacturing of the treated material. This is a presence/absence indicator. If any restrictions limiting secondary manufacture appear on the label, then Secondary Manufacture should be selected.

Entry type: presence/absence selection.

Validation Procedures:

5.2.5.4.26.1 There is zero to one Secondary Manufacturing requirements.
5.2.5.4.26.2 If a Secondary Manufacturing restriction is provided at the Product or Site level, then there should not also be Secondary Manufacturing provided at the Scenario level.

Xml Code Snippet:

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
   <substanceAdministration>
      <componentOf>
         <protocol>

            <!-- other elements -->

            <!-- Secondary Manufacturing -->
            <component>
               <requirement>
                  <code code="1005337"
codeSystem="2.16.840.1.113883.6.275.1"
                        displayName="Secondary Manufacturing"/>
               </requirement>
            </component>
```