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

(DRAFT)

**** This is a draft document. Its purposes are not intended for use of building an XML Schema document for later submission to EPA. ****

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1 Introduction

The Environmental Protection Agency's (EPA) SmartLabel Project is an electronic system for submission of Pesticide Product Labels, related use information, and tolerance data. The SmartLabel system allows pesticide manufacturers to develop and submit Pesticide Product 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 Product 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 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 EPA. It is intended that the companion document on the **SmartLabel Vocabulary Guide Version 3.xlsx** is used in concurrence with this guidance. Additionally, information on technical conformance criteria is included to provide the blueprint for the coding utilized in the SPL Extensible Markup Language (XML) model.

The Agency hosts a SPL Builder on 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 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 pass validation and be submitted through the Agency's CDX portal. *EPA's 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 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 the header and body of the SmartLabel document independent of the exchanged information; *i.e.,* the blueprint for the XML form. The second part of the document (*Section 3*) describes the standard/model used and the technical conformance criteria used to enter information into the Pesticide Product Label. The third part of the document (*Section 4*) describes the standard/model used and the technical conformance criteria used to enter information into the Use Index.

Each section of the document is broken into subsections that represent 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.

1.2 Document Information (Package Information Section)

- **Document Name** is an optional field on the 'Document Information' screen of the builder application. Its value is not added to the XML schema and it is not submitted. Saving locally will capture this value in the .zip filename instead of the default "Document ID" filename.
- **Company Name** identifies the name of the organization registered with EPA and associated with the pesticide product. It is linked with the **Company Number** below listed; both of which are populated from the CDX account of the user who created the SmartLabel package. See section **2.1.3 Author Information** below.
- **Registration Number** is a unique identifier for each registered pesticide product. It is separated into two parts comprised of an **EPA Company Number** and **Product Number**. While both numbers are captured together on the' Document Information' screen of the SmartLabel builder application, each number is stored in its own location in the respective XML documents. See sections **3.6.1.1 Product Number** and **4.3.1.1 Product Number** for more information on Product Numbers.
- **EPA Company Number** is a unique identifier assigned by EPA to the registered organization listed under **Company Name**. It is populated from the CDX account of the user who created the SmartLabel package. See section **2.1.3 Introduction** below.
- **Product Number** is a unique identifier assigned by EPA to the registered pesticide product. This number is combined with an **EPA Company Number** to form a **Registration Number** unique to each registered pesticide product. While this number is entered on the Document Information screen of the SmartLabel builder application, it is captured in the Product Profile section of the Pesticide Product Label document and Product Identification section of the Use Index document. See sections **3.6.1.1 Product Number** and **4.3.1.1 Product Number** for more information.

1.3 Document ID Numbering

- [Document Type] . [Section] . [Sub-section] . [Data Element] . [Validation Error ID]
- Section = screen in the Label Doc or Section = Level in the Use Index Doc
- In the Label document, section statements are synonymous with 'Sub-section'; e.g., 'Ingredient Statement' applies to that sub-section but also to the statement made in the respective section text area.
- In the Use Index document, 'Section' is synonymous with the level; e.g., Product Level, Site Level, Scenario Level.

1.4 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 their submission is correct. Additionally, the validation procedures are written as specific and operational so that they may be checked by systems processing SmartLabel documents. Therefore, some validation procedures contain information that refers specifically to SmartLabel standards. Validation procedures that are meant to be used as a check-list when entering information are specified in ***black text***, while SPL technical conformance criteria that are needed to program the XML builder are specified in *grey text*. Validation rules typically include information such as: if a section is required, the number of times a section can be used (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 message has an ID number. These validation messages and ID numbers are generally stable over time but may change between versions of the document. Although rare, new validations may be inserted between existing versions. Normally however, new validations are appended to the end of their respective sub-sections.

Validation Rules:

ID Numbers	Validation Error Messages
Linked validation ID number denoting location of error	Human readable text stating specific cause of validation error

XML Code Snippet:

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

2 Overview of SPL Technical Conformance Criteria

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. SPL documents include both 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. EPA's 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 EPA, and technical conformance criteria for SPL documents used by EPA's OPP to create the XML builder.

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

2.1 HL7 SPL Header

2.1.0 General

The following validation rules apply generally to all SmartLabel files submitted to EPA.

Validation Procedures:

ID Numbers	Validation Error Messages
2.1.0.1.1	XML is well formed and valid against the schema
2.1.0.1.2	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.
2.1.0.1.3	There are no spaces in codes
2.1.0.1.4	Codes do not have a codeSystemName attribute
2.1.0.1.5	Display names are case insensitive.
2.1.0.1.6	There are no spaces in id extensions
2.1.0.1.7	Letters in Globally Unique Identifiers (GUID) are lower case
2.1.0.1.8	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 codeSystem)
2.1.0.1.9	Characteristics have a class code of "OBS" or no class code at all
2.1.0.1.10	There is no confidentiality code on anything but inactive ingredients, registrant, and assigned establishments outside establishment registrations
2.1.0.1.11	If there is a confidentiality code, then the code is "B" and the codeSystem is 2.16.840.1.113883.5.25

2.1.1 XML References

This information includes the location of the current style sheet for EPA's 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:

ID Numbers	Validation Error Messages
2.1.1.1.1	XML reference is for version 1.0 and encoding "UTF-8"
2.1.1.1.2	There is an xml-stylesheet reference to https://cdxnodengn.epa.gov/cdx-SmartLabel/public/stylesheet/spl.xsl
2.1.1.1.3	The schemaLocation of the urn:hl7-org:v3 namespace is provided as https://cdxnodengn.epa.gov/cdx-SmartLabel/public/schema/SPL.xsd
2.1.1.1.4	There are no processing instructions other than the XML and xml-stylesheet declarations
2.1.1.1.5	There are no comments
2.1.1.1.6	SPL file name is the document id followed by ".zip"
2.1.1.1.7	A submission contains only the SPL file whose name ends in ".zip" and, if appropriate, associated labeling files whose name ends in ".pdf" or image files whose name ends in ".jpg" or ".jpeg"
2.1.1.1.8	All files associated with the SPL document are referenced from that SPL document

Figure 1: XML References 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">
```

2.1.2 Document Information

This information 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> is a Globally Unique Identifier (GUID) and is unique for each version of the document. Letters used in a GUID are lower case.
- The <code> provides information on the document type.
- The <title> data element is used for the document title, 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> provides a date reference to the SPL version including the year, month and day as yyyymmdd.
- The <setId> is a GUID for the document that remains constant through all versions/revisions of the document.
- The <versionNumber> 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:

ID Numbers	Validation Error Messages
2.1.2.1.1	There is one Document ID per Document Type
2.1.2.1.2	Document ID is a Globally Unique Identifier (GUID) captured as <id root> under <document>
2.1.2.1.3	Document ID does not have an extension
2.1.2.1.4	Document ID must be unique and cannot match any other ID within the document
2.1.2.1.5	Document ID (id root) must be unique across all documents within EPAs database
2.1.2.1.6	Each document type has a code
2.1.2.1.7	Each document type code and displayName comes from codeSystem 2.16.840.1.113883.6.275.1
2.1.2.1.8	Each document type displayName must match the respective code
2.1.2.1.9	There are no figures in the title
2.1.2.1.10	There is an "Effective Date" captured as <effectiveTime>
2.1.2.1.11	Effective Date has the precision of four digit year, two digit month, and two digit day in the format YYYYMMDD
2.1.2.1.12	There is one Set ID captured as <setId>
2.1.2.1.13	Set ID must be a Globally Unique Identifier (GUID)
2.1.2.1.14	Set ID does not match any other <setId> within the document
2.1.2.1.15	There is one document Version captured as <versionNumber>
2.1.2.1.16	Version value must be a whole number greater than 0 (zero)

2.1.3 Author Information

This section provides basic information about the business responsible for the product, including the Company Name and Company Number. See section **1.2 Document Information (Package Information Section)** for additional information.

- The <name> (also known as ***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.
- The <id extension> (also known as ***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.

Validation Procedures:

ID Numbers	Validation Error Messages
2.1.3.1.1	There is one EPA Company Number captured as <id extension/>
2.1.3.1.2	EPA Company Number has a root of 2.16.840.1.113883.6.275.1
2.1.3.1.3	There is one Company Name is captured as <name>

Figure 2: Author Information XML Code Snippet

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

2.2 HL7 SPL Body

2.2.0 General

The body of an SPL document can include structured text (e.g., product labeling), structured values (e.g., percent active ingredient), and/or specific data elements from picklists (e.g., active ingredients).

Figure 3: SPL Body 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.

Figure 4: Sections XML Code Snippet

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

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

Sections and subsections have an 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 rendered using the standard style sheet.

Figure 5: Section Text 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 (<code>) 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 an SPL document 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.

Figure 6: Sub-Section XML Codes 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 properly use and display this information.
- 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:

ID Numbers	Validation Error Messages
2.2.1.1.1	Each section has zero to many subsections
2.2.1.1.2	Each section and subsection has a <section ID> captured as <id root> and does not have an extension
2.2.1.1.3	<section ID> (id root) must be a Globally Unique Identifier (GUID)
2.2.1.1.4	<section ID> (id root) cannot match any other IDs in the document
2.2.1.1.5	<section ID> (id root) does not match any ID other than the ID of the same section previously submitted
2.2.1.1.6	Each section and subsection has a section UID corresponding to a section name captured as code "value"
2.2.1.1.7	Section UID (code "value") comes from codeSystem 2.16.840.1.113883.6.275.1
2.2.1.1.8	Each section and sub-section has a name captured as displayName "value"
2.2.1.1.9	Section UID (code "value") and displayName "value" are from codeSystem 2.16.840.1.113883.6.275.1 and must match
2.2.1.1.10	Each section optionally has an effectiveTime with at least the precision of day in the format YYYYMMDD
2.2.1.1.11	There are no figures in the <title> for a section or subsection

2.2.2 Document Inputs

2.2.2.1 Text

The human readable text content of SmartLabel 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 an SPL document 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.

Figure 7: Section Text XML 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>
```

2.2.2.2 Font Effects

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

Figure 8: Font Effects XML 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:

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

Figure 9: Font Effects (Continued) XML Snippet

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

Can also be represented as:

Figure 10: Font Effects (Continued 2) XML Snippet

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

The values for <styleCode> for font effects are bold, italics, and underline. To assist visually impaired users, 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 screen reader programs.

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

2.2.2.3 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 utilizes UTF-8, any Unicode character can be included. 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 style sheet 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".

2.2.2.4 Footnotes

The SPL schema includes a specific footnote element, <footnote>. Footnotes are rendered automatically by the standard SPL style sheet. <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 style sheet 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.

2.2.2.5 Lists

All lists are marked 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 style sheet.

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:

Figure 11: List 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>
```

2.2.2.6 Tables

Tables can be created with the full structure (header (e.g., for column names), body (e.g., for table rows) 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 style sheet 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.

2.2.2.7 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 style sheet 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.

2.2.2.8 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">.

Validation Procedures:

ID Numbers	Validation Error Messages
2.2.2.8.1	Text is enclosed under <paragraph>, <list>, or <table> elements

Figure 12: Recent Major Change in Text Example 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>
```

2.2.2.9 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; e.g., ".jpg" or ".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 <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 style sheet does not resize or change the resolution of graphics files. Thus, all images are rendered in the browser as-is, with all characteristics of the actual graphic file itself. It is very important that the graphic file is edited to dimensions appropriate for its presentation within the browser to ensure that a graphic will appear as desired. If not, the appearance of the graphic may not be consistent with the narrative content and reduce the readability of the file. Images should be Joint Photographic Experts Group (JPEG)/JPG file type with appropriate pixels per inch for viewing the standard style sheet using a web browser.

Validation Procedures:

ID Numbers	Validation Error Messages
2.2.2.9.1	There is <text> associated with an image.
2.2.2.9.2	Image mediaType is "image/jpeg" or "image/jpg".
2.2.2.9.3	Image <value> xsi:type is "ED".
2.2.2.9.4	Image <reference> value is the filename for a valid image.
2.2.2.9.5	Size of image file is less than 1 MB.
2.2.2.9.6	Image file must be JPEG with name extension ".jpg" or ".jpeg".
2.2.2.9.7	Image components are referenced at least once in the text of any section.
2.2.2.9.8	Image reference in <text> has an image <observationMedia> element with a matching ID in the same document.

Figure 13: Images XML Code Snippet

```
<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 Pesticide Product Label

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

This document captures data in text boxes, as terms from a picklist, 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 help the user select 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.

3.1 Pesticide Product Labeling SPL Header

3.1.0 Section in General

This section provides basic information for the identity of the Pesticide Product Labeling document, its type, title, date, and versioning as a member of a document set. This information is captured in the Document Information section of the application and stored as part of the Pesticide Product Labeling XML schema. See section **1.2 Document Information** above.

3.1.1 Document Type

This is the header name of the SmartLabel document providing general subject matter of the Pesticide Product Label.

Entry type: "Document type" picklist selection.

Validation Procedures

ID Numbers	Validation Error Messages
3.1.1.0.1	There is one Pesticide Product Label "Document Type" with a code of 3565715.
3.1.1.0.2	There is one Pesticide Product Label "Document Type" with a displayName of "Pesticide Product Label".

Figure 14: Pesticide Product Label Document Type XML Code Snippet

```
<document>
 <code code="3565715"
       codeSystem="2.16.840.1.113883.6.275.1"
       displayName="Pesticide Product Label"/>
```

3.1.2 Author Information

This is the **Company Name** of the organization associated with the registered pesticide product. See above sections **1.2 Document Information** and **2.1.3 Author Information**.

3.1.2.1 Company Name

Identifies the organization registering the product using the company name registered with the agency that is associated with the below entered company number.

Entry type: Text.

Validation Procedures

ID Numbers	Validation Error Messages
3.1.2.1.1	There is one Company Name (author) captured as <name> under <representedOrganization>.
3.1.2.1.2	Only <id> and <name> should be present under <representedOrganization>.
3.1.2.1.3	Company Name matches the name in the EPA Company Number list.

3.1.2.2 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

ID Numbers	Validation Error Messages
3.1.2.2.1	There is one EPA Company Number captured as <id extension> under <representedOrganization>.

Figure 15: Product Labeling Author Information 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>
```

3.2 Pesticide Product Labeling SPL Body

3.2.0 Section 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:

ID Numbers	Validation Error Messages
3.2.0.0.1	Each section has zero to many subsections.
3.2.0.0.2	Each section and subsection has a <section ID> captured as <id root> and does not have an extension.
3.2.0.0.3	<section ID> (id root) must be a Globally Unique Identifier (GUID).
3.2.0.0.4	<section ID> (id root) cannot match any other IDs in the document.
3.2.0.0.5	<section ID> (id root) does not match any ID other than the ID of the same section previously submitted.
3.2.0.0.6	Each section and subsection has a section UID corresponding to a section name and captured as code "value".
3.2.0.0.7	Section UID (code "value") comes from codeSystem 2.16.840.1.113883.6.275.1.
3.2.0.0.8	Each section and sub-section has a name captured as displayName "value" in the Pesticide Product Label XML schema; e.g., "Directions for Use".
3.2.0.0.9	Section UID (code "value") and displayName "value" are from codeSystem 2.16.840.1.113883.6.275.1 and must match.
3.2.0.0.10	Each section optionally has an effectiveTime with at least the precision of day in the format YYYYMMDD.
3.2.0.0.11	There are no figures in the <title> for a section or subsection.

Figure 16: Pesticide Product Label Sections in General 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">
      ...
```

3.2.1 Pesticide Product Label sections in General

The Pesticide Product Label document is divided into sections. Each section of the Pesticide Product Label document can contain zero to many subsections. Information regarding the types of data provided in each section and the respective subsections is noted in **Section 3 Pesticide Product Label** of this Implementation Guide. Only data elements (e.g., section text areas) containing inputs inside the Pesticide Product Label of the application builder are added to the XML schema to be submitted.

3.3 Restricted Use Pesticide (RUP) Section

3.3.0 Section in General

The content of this section describes if a Pesticide Product has the potential to cause unreasonable adverse effects to the environment and/or injury to applicators or bystanders without added restrictions. In general, it describes why the product is considered RUP and provides a summary statement of the terms of the restriction.

- 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.”
- 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 Label Review Manual (LRM): Chapter 6.

3.3.1 RUP Statement (Section Text)

If a product is classified as a RUP, information regarding that classification is found in the Pesticide Product Label RUP section text area provided here. If this section applies to the product, enter the appropriate text in this section text area. If this section does not apply to the product, leave the section text area blank.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.3.1.0.1	There is one Restricted Use Pesticide section with a code of 3144193 and a displayName of "Restricted Use Pesticide".
3.3.1.0.2	Restricted Use Pesticide section <title> and displayName must match.
3.3.1.0.3	Restricted Use Pesticide section has no sub-sections.
3.3.1.0.4	If the product is not considered a RUP, then leave text element blank ("text" can be null).

Figure 17: RUP Section 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"/>
```

3.4 Ingredient Statement Section

3.4.0 Section in General

The content of this section provides information regarding the ingredients contained in a pesticide product. In addition to inputs made to the Ingredient Statement section text area, information is also provided per the respective sub-sections including: Active Ingredients, Identified Inert Statement, and Deterioration/Expiration Statement.

3.4.1 Ingredient Statement (Section Text)

Enter the appropriate text in this section text area if this section applies to a product. If this section does not apply to a product, leave this section text area blank.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.4.1.0.1	There is one Ingredient Statement section with a code of 3144198 and a displayName of "Ingredient Statement".
3.4.1.0.2	Ingredient Statement section <title> and displayName must match.

3.4.1.1 Active Ingredients

This sub-section identifies and characterizes the active ingredients contained in a product captured as EPA Registry Name and Systematic Name including: a listing of active ingredient(s) and their respective nominal concentrations (expressed as a percentage); and 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).

- **Percent Active Ingredient** is the strength of an active ingredient expressed as a percentage. For products which express the strength of an active ingredient as a range, input the high number of the range. For products which express the strength of an active ingredient as a qualified value (e.g., ≤) enter the value identified on the label.
- **Factoring Term Ingredient** can be optionally specified for certain chemical types. 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.
- **Percent Factoring Term** is 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.
- Reference: 40 CFR 156.10(g) and LRM: Chapter 5.

Entry type: Substance picklist selection and value.

Validation Procedures

ID Numbers	Validation Error Messages
3.4.1.1.1	There is at least one or more Active Ingredient(s) with name and code provided under <ingredientSubstance>.
3.4.1.1.2	There is one Percent Active Ingredient per Active Ingredient with a unit code of 3627136 and a displayName of "%".
3.4.1.1.3	Percent Active Ingredient value is a number.
3.4.1.1.4	There is zero or one Factoring Term per Active Ingredient with name and code provided under <activeMoiety>.
3.4.1.1.5	There is one Percent Factoring Term per Factoring Term with a unit code of 3627136 and a displayName of "%".
3.4.1.1.6	Percent Factoring Term value is a number.

Figure 18: Active Ingredient 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>
      <name use="OR">EPA Registry 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>
```

3.4.2 Identified Inert Statement Sub-Section (3565732)

This label sub-section includes statements which identify toxic ingredients, petroleum distillates, sodium nitrite, or other compounds which are required to be disclosed. If this sub-section applies to a product, enter the appropriate text in this sub-section text area. If this sub-section does not apply to the product, leave the sub-section text area blank.

- Reference: LRM Chapter 5.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.4.2.0.1	There is one Identified Inert Statement sub-section with a code of 3565732 and a displayName of “Identified Inert Statement”.
3.4.2.0.2	Identified Inert Statement sub-section <title> must match the displayName.
3.4.2.0.3	If Identified Inert Statement is not applicable to the product, leave the <text> element blank.

Figure 19: Identified Inert Statement Sub-section 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"/>
```

3.4.3 Deterioration/Expiration Statement Sub-Section (3144196)

This label sub-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 sub-section of the label. If this sub-section applies to the product, enter the appropriate text in this sub-section text area. If this sub-section does not apply to the product, leave the sub-section text area blank.

- Examples: “Not for sale or use after (date)” or “Degrades with age…”
- Reference: 40 CFR 156.10(g)(6)(i); LRM Chapter 5.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.4.3.0.1	There is one Deterioration/Expiration Statement sub-section with a code of 3144196 and a displayName of “Deterioration/Expiration Statement”.
3.4.3.0.2	Deterioration/Expiration Statement sub-section <title> must match the displayName.
3.4.3.0.3	If Deterioration/Expiration Statement is not applicable to the product, leave the <text> element blank.

Figure 20: Deterioration/Expiration Statement 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"/>
```

3.5 Child Hazard Warning/Signal Word Section

3.5.0 Section in General

This content section and sub-sections include statements and images regarding the Child Hazard Warning and the Signal Word. Free text and images regarding the Child Hazard Warning are added in the section text area for possible contact with children during distribution, storage, and/or use. Associated Signal Word and Signal Word Qualifiers are added by selecting inputs from the respective, pre-determined EPA lists.

- Example: Child Hazard Warning free text may include "Keep out of Reach of Children" with an image of a skull and cross-bones in the section text area. The associated Signal Word may include “Danger” with a Signal Word Qualifier of "Poison [skull and cross-bones]”.

3.5.1 Child Hazard Warning/Signal Word Statement (Section Text)

If a pesticide product label should contain statements regarding child safety, including KOROC, free text should be entered in the section text area. Images may or may not be accompany the text. If this section does not apply to the product, leave the section text area blank.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.5.1.0.1	There is one Child Hazard Warning/Signal Word section with a code of 3567150 and a displayName of "Child Hazard Warning/Signal Word".
3.5.1.0.2	Child Hazard Warning/Signal Word section <title> must match the displayName.

3.5.1.1 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:

ID Numbers	Validation Error Messages
3.5.1.1.1	Signal Word is required and cannot be null.
3.5.1.1.2	Signal Word code and displayName must come from the list "Signal Word" (1004401) and are captured under <asSpecializedKind>.
3.5.1.1.3	Signal Word codeSystem is 2.16.840.1.113883.6.275.1.

3.5.1.2 Signal Word Qualifier

This label attribute is the optional selection of a term to accompany the signature word (e.g., Peligro).

- Reference: LRM Chapter 7 and 10; 40 CFR 156.206(e).

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

Validation Procedures:

ID Numbers	Validation Error Messages
3.5.1.2.1	There is zero or one Signal Word Qualifier per Signal Word.
3.5.1.2.2	Signal Word Qualifier code and displayName must come from the list "Signal Word Qualifier" and are captured under <qualifier>.
3.5.1.2.3	Signal Word Qualifier codeSystem is 2.16.840.1.113883.6.275.1.
3.5.1.2.4	There is zero or one "image" included in the "Child Hazard Warning/Signal Word" section.

Figure 21: Child Hazard Warning/Signal Word XML Code Snippet

```
<component>
 <section ID="Lac57fb2d-2975-42ee-a868-e3c5020ba88a">
  <id root="ac57fb2d-2975-42ee-a868-e3c5020ba88a"/>
  <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/>
  <subject>
   <templateId root="2.25.103462320756511569739271315614353179931"
               extension="XX-Builder-XX"/>
    <manufacturedProduct>
     <manufacturedProduct>
      <asSpecializedKind>
       <generalizedMaterialKind>
        <code code="3143676"
              codeSystem="2.16.840.1.113883.6.275.1"
              displayName="Danger">
         <qualifier xsi:type="CR">
          <value code="3143691"
                 codeSystem="2.16.840.1.113883.6.275.1"
                 displayName="Peligro"/>
         </qualifier>
        </code>
       </generalizedMaterialKind>
      </asSpecializedKind>
     </manufacturedProduct>
    </manufacturedProduct>
   </subject>
  </section>
 </component>
<component>
```

3.6 Product Profile

3.6.0 Section in General

This content section includes information that is unique to a pesticide product and that generally appears on the front page of a pesticide product label, including: Primary Brand Name, Alternate Brand Name(s), Product Number, EPA Company Number, Company Name, Pesticide Classification, Net Contents or Net Weight, and Batch Code. This section includes the paragraph or phrase typically found under the product name of the label describing the type of product, formulation, its uses, pests it controls, and other categories or descriptors (e.g., resistance management category). NOTE: not all information captured in this section is provided from the Product Profile screen of the SmartLabel builder application. See above **Section 1.2 Document Information** for additional information.

3.6.1 Product Profile Statement (Section Text)

Free text entered in the Product Profile section text area includes statements and/or phrases typically found under the product name describing the type of product, its formulation, its uses, pests it controls, and other categories or descriptors (e.g., resistance management category). This content section may also include other descriptors for the product that are NOT contained in the Ingredient Statement, Precautionary Statements, Directions for Use, Warranty/Disclaimer Statement, or Marketing/Advertising Claims sections.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.6.1.0.1	There is one Product Profile section with a code of 3144190 and a displayName of "Product Profile".

ID Numbers	Validation Error Messages
3.6.1.0.2	Product Profile section <title> must match the displayName.

3.6.1.1 Product Number

This is a unique number assigned to the product by EPA. This number is combined with the **EPA Company Number** to form a unique identifier for each registered pesticide product, known as the **EPA Registration Number**. While this number exists in the Product Profile section per the Pesticide Product Label XML schema, it is captured with the Package Information of the 'Document Information' section of the application. See above **Section 1.2 Document Information** for additional information.

Entry type: Numeric text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.6.1.1.1	There must be one and only one Product Number per Pesticide Product Label.

3.6.1.2 Primary Brand Name

Primary Brand Name is the product brand name and it is required. There may only be one Primary Brand Name associated with a registered pesticide product. It cannot match any Alternate Brand Name(s), should any be listed.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.6.1.2.1	There must be one and only one Primary Brand Name per Pesticide Product Label.

3.6.1.3 Packaged Form

Describes the physical state and attributes of the product as packaged. If the product is a liquid, the type of liquid (e.g., Solution, Suspension, Emulsion, or Gel/Grease/Paste) is selected. If the product is a solid, the type of solid (e.g., 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. 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: "*Physical Form*" picklist selection.

Validation Procedures:

ID Numbers	Validation Error Messages
3.6.1.3.1	There must be one and only one Packaged Form per Pesticide Product Label.
3.6.1.3.2	Packaged Form is from the list "Physical Form" and captured as <formCode>.

3.6.1.4 Pesticide Classification(s)

Describes a product according to the type of pest targeted and the function of a pesticide against the pest (e.g., fungicide, herbicide, disinfectant).

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

Validation Procedures:

ID Numbers	Validation Error Messages
3.6.1.4.1	There is at least one to many Pesticide Classification(s) per Pesticide Product Label.
3.6.1.4.2	Pesticide Classification(s) is from the list "Pesticide Classifications".

3.6.1.5 Alternate Brand Name(s)

Includes any names associated with the registered pesticide product, other than the Primary Brand Name, under which this product may be sold. There may be zero to many Alternate Brand Names.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.6.1.5.1	There are zero to many Alternate Brand Name(s) per Pesticide Product Label.
3.6.1.5.2	Alternate Brand Name(s) must be unique and cannot be duplicated.
3.6.1.5.3	Alternate Brand Name(s) cannot match the Primary Brand Name.

Xml Code Snippet:

Figure 22: Product Profile 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>
```

3.7 Precautionary Statements

3.7.0 Section in General

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:

ID Numbers	Validation Error Messages
3.7.0.0.1	There is one Precautionary Statements section with a code of 3144199 and a displayName of "Precautionary Statements".
3.7.0.0.2	Precautionary Statements section <title> must match the displayName.

XML Code Snippet:

Figure 23: Precautionary Statements 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"/>
```

3.7.1 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. Additionally, this section 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 a product, enter the appropriate text in this section text area. If this section does not apply to a product, leave the section text area blank.

- Reference: 40 CFR 156.68; LRM Chapter 7.

Entry type: Text.

Validation Procedures

ID Numbers	Validation Error Messages
3.7.1.0.1	There is one First Aid sub-section with a code of 3144200 and a displayName of "First Aid".
3.7.1.0.2	First Aid sub-section <title> must match the displayName.

Figure 24: FIRST Aid Sub-Section 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"/>
```

3.7.2 Hazards to Humans and Domestic Animals (3144205)

Includes "Precautionary Statements", a product's signal word, and statement(s) that describe a 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 a product, enter the appropriate text in this section text area. If this section does not apply to a product, leave the section text area blank.

- Reference: 40 CFR 156.70; LRM Chapter 7.

Entry type: Text.

Validation Procedures

ID Numbers	Validation Error Messages
3.7.2.0.1	There is one Hazards to Humans and Domestic Animals sub-section with a code of 3144205 and a displayName of "Hazards to Humans and Domestic Animals".
3.7.2.0.2	Hazards to Humans and Domestic Animals sub-section <title> must match the displayName.

Figure 25: Hazards to Humans and Domestic Animals Sub-Section 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"/>
```

3.7.3 Personal Protective Equipment (PPE) (3144206)

Lists all of the required 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 a product, enter the appropriate text in this section text area. If this section does not apply to a product, leave the section text area blank.

- Reference: 40 CFR 170.240; LRM Chapter 10.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.7.3.0.1	There is one Personal Protective Equipment sub-section with a code of 3144206 and a displayName of "Personal Protective Equipment".
3.7.3.0.2	Personal Protect Equipment sub-section <title> must match the displayName.

Figure 26: PPE Sub-Section 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"/>
```

3.7.4 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 a product, enter the appropriate text in this section text area. If this section does not apply to a product, leave the section text area blank.

- Example: When handlers use closed systems, enclosed cabs, or aircraft, in a manner that meets the requirements listed in the 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.

- Reference: 40 CFR 170.240 (d) (4-6). LRM Chapter 10.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.7.4.0.1	There is one Engineering Controls Statement sub-section with a code of 3144207 and a displayName of "Engineering Controls Statement".
3.7.4.0.2	Engineering Controls Statement sub-section <title> must match the displayName.

Figure 27: Engineering Controls Statement Sub-Section 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"/>
```

3.7.5 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 and other Agency documents that this section is required for all occupational use products, both WPS and non-WPS. If this section applies to a product, enter the appropriate text in this section text area. If this section does not apply to a product, leave the section text area blank.

- 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.”
- Reference: 40 CFR 170.240, 40 CFR156.200-212. LRM Chapter 10.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.7.5.0.1	There is one User Safety Requirements sub-section with a code of 3144208 and a displayName of "User Safety Requirements".
3.7.5.0.2	Use Safety Requirements sub-section <title> must match the displayName.

Figure 28: User Safety Requirements 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"/>
```

3.7.6 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 a product, enter the appropriate text in this section text area. If this section does not apply to a product, leave the section text area blank.

- 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.”
- Reference: PR Notice 93-7, Supplement Three. LRM Chapter 10.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.7.6.0.1	There is one Use Safety Recommendations sub-section with a code of 3144209 and a displayName of "User Safety Recommendations".
3.7.6.0.2	User Safety Recommendations sub-section <title> must match the displayName.

Figure 29: Use Safety Recommendations 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"/>
```

3.7.7 Environmental Hazards (3144210)

Provides precautionary information on potential hazards to the environment from transport, use, storage, and/or spill of the product based on environmental fate and toxicity data. These hazards may be to water, soil, air, and/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). If this section applies to a product, enter the appropriate text in this section text area. If this section does not apply to a product, leave the section text area blank.

- Reference: 40 CFR 156.80-85; LRM Chapter 8.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.7.7.0.1	There is one Environmental Hazards sub-section with a code of 3144210 and a displayName of "Environmental Hazards".
3.7.7.0.2	Environmental Hazards sub-section <title> must match the displayName.

Figure 30: Environmental Hazards Sub-section 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"/>
```

3.7.8 Physical and Chemical Hazards (3144212)

Includes language and symbols regarding physical and/or chemical hazards for the product, as well as the various required precautions identified in the product chemistry review. If this section applies to a product, enter the appropriate text in this section text area. If this section does not apply to a product, leave the section text area blank.

- Example: “Combustible. Do not use or store near heat or open flame.”
- Reference: 40 CFR 156.78. LRM Chapter 9.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.7.8.0.1	There is one Physical and Chemical Hazards sub-section with a code of 3144212 and a displayName of "Physical and Chemical Hazards".
3.7.8.0.2	Physical and Chemical Hazards sub-section <title> must match the displayName.

Figure 31: Physical and Chemical Hazards Sub-section 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"/>
```

3.8 Directions for Use

3.8.0 Section in General

The content for this label section is contained within the main section and its sub-sections. Information presented here in a clear, concise, and effective manner describes how a product can legally be used and how a product must not be used. It is critical to distinguish the statements that are intended to be enforceable from those that are included for informational purposes.

- Reference 40 CFR 156.10(i).

3.8.1 Directions for Use Statement (Section Text)

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 above noted. 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:

ID Numbers	Validation Error Messages
3.8.1.0.1	There is one Directions for Use section with a code of 3144213 and displayName of "Directions for Use".
3.8.1.0.2	Directions for Use section <title> must match the displayName.
3.8.1.0.3	The following statement must be present in the Directions for Use statement section <text>: "IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING."
3.8.1.0.4	If product is a RUP, then the text "Restricted Use Pesticide" should appear in the Directions for Use section <text>.

Figure 32: Directions for Use Section 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"/>
```

3.8.2 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 a product, enter the appropriate text in this section text area. If this section does not apply to a product, leave the section text area blank.

- Reference: WPS-required language can be found in CFR 156.206.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.8.2.0.1	There is one Agricultural Use Requirements sub-section with a code of 3144215 and a displayName of "Agricultural Use Requirements".
3.8.2.0.2	Agricultural Use Requirements sub-section <title> must match the displayName.

Figure 33: Agricultural Use Requirements Sub-section 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"/>
```

3.8.3 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 WPS 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. If this section applies to a product, enter the appropriate text in this section text area. If this section does not apply to a product, leave the section text area blank.

- This section only needs to be entered if a label includes both WPS and non-WPS use sites.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.8.3.0.1	There is one Non Agricultural Use Requirements sub-section with a code of 3144216 and a displayName of "Non Agricultural Use Requirements".
3.8.3.0.2	Non Agricultural Use Requirements sub-section <title> must match the displayName.

Figure 34: Non Agricultural Use Requirements Sub-section 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"/>
```

3.8.4 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 a product, enter the appropriate text in this section text area. If this section does not apply to the product, leave a section text area blank.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.8.4.0.1	There is one Resistance Management" sub-section with a code of 3144217 and a displayName of "Resistance Management".

ID Numbers	Validation Error Messages
3.8.4.0.2	Resistance Management sub-section <title> must match the displayName.

Figure 35: Resistance Management Sub-section 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"/>
```

3.8.5 Spray Drift (3144230)

Includes any mandatory spray drift prevention language as well as any advisory language that is applicable to a product. If this section applies to a product, enter the appropriate text in this section text area. If this section does not apply to a product, leave the section text area blank.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.8.5.0.1	There is one Spray Drift Management sub-section with a code of 3144230 and a displayName of "Spray Drift Management".
3.8.5.0.2	Spray Drift Management sub-section <title> must match the displayName.

Figure 36: Spray Drift Management Sub-section 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"/>
```

3.8.6 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 a product, enter the appropriate text in this section text area. If this section does not apply to a product, leave the section text area blank.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.8.6.0.1	There is one Rotational Crop Intervals sub-section with a code of 3144229 and a displayName of "Rotational Crop Intervals".
3.8.6.0.2	Rotational Crop Intervals sub-section <title> must match the displayName.

Figure 37: Rotational Crop Interval Sub-section 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"/>
```

3.8.7 Seed Bag Labeling Requirements (3144214)

Contains instructions to the applicator/seed treater regarding labeling requirements for bags containing treated seed. If this section applies to a product, enter the appropriate text in this section text area. If this section does not apply to a product, leave the section text area blank.

- If it applies, Seed Bag Labeling must include the specific 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).

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.8.7.0.1	There is one Seed Bag Labeling Requirements sub-section with a code of 3144214 and a displayName of "Seed Bag Labeling Requirements".
3.8.7.0.2	Seed Bag Labeling Requirements sub-section <title> must match the displayName.

Figure 38: Seed Bag Labeling Requirements Sub-section 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"/>
```

3.8.8 Storage and Disposal Subsection (3144244)

Contains information on storage, pesticide disposal, and container handling/disposal. This subsection has further data elements, see details in **Section 3.8.8.1 Container Type** 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 Federal Insecticide, Fungicide, and Rodenticide Act (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:

ID Numbers	Validation Error Messages
3.8.8.0.1	There is one Storage and Disposal" sub-section with a code of 3144244 and a displayName of "Storage and Disposal".
3.8.8.0.2	Storage and Disposal sub-section <title> must match the displayName.

Figure 39: Storage and Disposal Sub-section 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"/>
```

3.8.8.1 Container Type

Identifies the types of containers in which a product is packaged.

Entry type: "*FormCode*" picklist selection.

Validation Procedures:

ID Numbers	Validation Error Messages
3.8.8.1.1	Storage and Disposal sub-section has at least one "Container Type" captured as <formCode> under <asContent>.

3.8.9 Product Application Instructions/Information Subsection (3144218)

Includes any product application instructions that are consistent across all labeled use sites not described in the above sections. Information in this sub-section includes: directions to 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; and tank mix and compatibility (includes instructions for diluting and/or mixing the product with other chemicals prior to application). If this section applies to a product, enter the appropriate text in this section text area. If this section does not apply to a product, leave the section text area blank.

- Reference Chapter 11, Section 11-22 of the LRM.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.8.9.0.1	There is one Product Application Instructions/Information sub-section with a code of 3144218 and a displayName of "Product Application Instructions/Information".
3.8.9.0.2	Product Application Instructions/Information sub-section <title> must match the displayName.

Figure 40: Product Application Instructions/Information Sub-section 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"/>
```

3.8.10 Use Site Application Instructions Subsection

This label section includes application instructions specific to a use site, such as application rate, number of applications, reapplication interval, application timing, target pest, site-specific restrictions, etc.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.8.10.0.1	There is at least one or more Use Site Application Instructions sub-sections with a code of 3144234 and a displayName of "Use Site Application Instructions".
3.8.10.0.2	Use Site Application Instructions sub-section <title> must match the displayName.

- **Use Site Application Instructions Data Elements** are consistent across all labeled use sites not described in the above sections. 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; and 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 LRM for more information on what to include in this section.

3.8.10.1 Use Site/Commodity

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 "Crop Use Sites" and "Non-Crop Use Sites" lists in the **SmartLabel Vocabulary Guide Version 3.xlsx** document for guidance.

- **Pesticide Action –** Identifies a pesticide's intended use (e.g., Action Against Pest, Action Against Plant Disease, Plant Regulator) at the named Use Site(s)/Commodities.

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

Validation Procedures:

ID Numbers	Validation Error Messages
3.8.10.1.1	There is at least one to many "Use Site/Commodity" entries.
3.8.10.1.2	Use Site(s)/Commodity has a code of 3810088 and a displayName of "Use Site/Commodity".
3.8.10.1.3	Use Site/Commodity displayName must match the code.
3.8.10.1.4	If there is a Use Site/Commodity entry listed then there must be a <value> element with code and displayName.
3.8.10.1.5	Use Site/Commodity <value> code must come from the list "Registered Use Site" under codeSystem 2.16.840.1.113883.6.275.1.
3.8.10.1.6	Use Site/Commodity <value> code must match the displayName.
3.8.10.1.7	There is at least one Pesticide Action associated with Use Site/Commodity.
3.8.10.1.8	Pesticide Action has an effect code.
3.8.10.1.9	Pesticide Action code must come from the list "Pesticide Action" under codeSystem is 2.16.840.1.113883.6.275.1.
3.8.10.1.10	Pesticide Action code must match the displayName.

3.8.10.2 Use Site Location

Gives a broad category-based description of where a pesticide treatment takes 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.

Validation Procedures:

ID Numbers	Validation Error Messages
3.8.10.2.1	There is at least one to many Use Site Location(s).
3.8.10.2.2	Use Site Location(s) is captured as code and displayName under <approachSiteCode>.

Figure 41: Use Site Application Instructions Sub-section 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 Plant Disease ...
      ... Pesticide Action - Plant Regulator ...
     </goal>
     <!-- Additional Pesticide Actions -->
     <goal typeCode="OBJF">
      ... Pesticide Action Against Pest ...
      ... Pesticide Action Against Plant Disease ...
      ... Pesticide Action - Plant Regulator ...
     </goal>
```

Figure 42: Use Site Application Instructions Sub-section XML Code Snippet (Continued)

```
    </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 Plant Disease ...
     ... Pesticide Action - Plant Regulator ...
    </goal>
   </substanceAdministration>
  </subject2>
 </section>
</component>
```

3.8.10.3 Action(s) Against Pest

Specifies that the pesticide's effect against a target pest. The selection of an action indicates the expected outcome of the pesticide when applied to said target pest; e.g., Attract, Kill, Prevent, or Repel.

- **Pesticide Action** identifies if an intended pesticide use at the named Use Site(s)/Commodities is an Action Against Pest, Action Against Plant Disease, or Plant Regulator Function.
- **Target Pest** identifies the specific pest(s) for which a pesticide may be used to prevent, destroy, repel, or mitigate.
- **Pest Stage** identifies the development stage(s) of a target pest when a pesticide should be applied.

Entry type: "*Actions Against Pest*" picklist selection.

Validation Procedures:

ID Numbers	Validation Error Messages
3.8.10.3.1	If Pesticide Action is "Action Against Pest" then there must be a Target Pest element.
3.8.10.3.2	Target Pest codes are from the list "Target" under codeSystem 2.16.840.1.113883.6.275.
3.8.10.3.3	Target Pest displayName must match the code.
3.8.10.3.4	Target Pest must have at least one or more Pest Stage(s) under <characteristic>.
3.8.10.3.5	Pest Stage has a code of 1004703 and a displayName of "Pest Stage".
3.8.10.3.6	If there is a Pest Stage then there must be a <value> element with code and displayName.
3.8.10.3.7	Pest Stage <value> codes are from the list "Pest Stage" under codeSystem 2.16.840.1.113883.6.275.1.
3.8.10.3.8	Pest Stage <value> displayName must match the code.

3.8.10.4 Action(s) Against Plant Disease

Specifies that the effect of a pesticide is against a target plant disease. The selection of an action here indicates the expected outcome of the pesticide is to treat an existing plant disease and/or prevent the emergence of one.

- **Pesticide Action** identifies if an intended use of a pesticide at the named Use Site(s)/Commodities is an Action Against Pest, Action Against Plant Disease, or Plant Regulator Function.
- **Plant Disease** identifies the specific plant disease(s) for which a pesticide may be used.

Entry type: "*Actions Against Plant Disease*" picklist selection.

Validation Procedures:

ID Numbers	Validation Error Messages
3.8.10.4.1	If Pesticide Action is "Action Against Plant Disease" then there must be a Plant Disease element.
3.8.10.4.2	Plant Disease codes are from the list "Plant Disease" under codeSystem 2.16.840.1.113883.6.275.1.
3.8.10.4.3	Plant Disease displayName must match the code.

3.8.10.5 Plant Regulator Function

Specifies that the effect of a pesticide is intended for plant regulation.

- **Pesticide Action** identifies if the intended use of a pesticide at the named Use Site(s)/Commodities is an Action Against Pest, Action Against Plant Disease, or Plant Regulator Function.
- **Plant Regulator Function** describes the intent of a pesticide as accelerating or retarding growth, or altering plant behavior or the produce of the plant.

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

Validation Procedures:

ID Numbers	Validation Error Messages
3.8.10.5.1	If Pesticide Action is "Plant Regulator Function" then there must be a Plant Regulator Function element.
3.8.10.5.2	Plant Regulator Function codes are from the list "Plant Regulator Function" under codeSystem 2.16.840.1.113883.6.275.1.
3.8.10.5.3	Plant Regulator Function displayName must match the code.

Figure 43: Pesticide Action – Plant Regulator 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>
```

3.9 Warranty/Disclaimer Statement

3.9.0 Section in General

The content for this label section is language describing the warranty and disclaimer statement, and/or terms of use for a pesticide product.

3.9.1 Warranty and Disclaimer Statement (Section Text)

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

- Reference: LRM Chapter 12.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.9.1.0.1	There is one Warranty/Disclaimer section with a code of 3144249 and a displayName of "Warranty/Disclaimer".
3.9.1.0.2	Warranty/Disclaimer section <title> must match the displayName.

Figure 44: Warranty/Disclaimer Section XML Code Snippet

```
<section ID="Section Link">
 <id root="Section UUID"/>
 <code code="3144249" codeSystem="2.16.840.1.113883.6.275.1"
     displayName="Warranty/Disclaimer"/>
 <title> Warranty/Disclaimer </title>
 <text/>
 <effectiveTime value="YYYYMMDD"/>
```

3.10 Marketing/Advertising Claims

3.10.0 Section in General

The content for this label section is a statement of something as a fact or an assertion on the label open to challenge which is accepted by EPA.

3.10.1 Marketing and Advertising Claims Statement (Section Text)

This section contains a comprehensive numbered list of optional language used to market a product or make claims about the effectiveness or characteristics of a product. If this section applies to a product, enter the appropriate text in this section text area. If this section does not apply to a product, leave the section text area blank.

- Reference: LRM Chapter 12.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
3.10.1.0.1	There is one Marketing/Advertising Claims section with a code of 3144194 and a displayName of "Marketing/Advertising Claims".
3.10.1.0.2	Marketing/Advertising Claims section <title> must match the displayName.

3.10.1.1 Certifications and Seals

Identifies third party seals or certifications displayed on the label and the associated text (e.g., 'Good housekeeping seal of approval').

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

Validation Procedures:

ID Numbers	Validation Error Messages
3.10.2.0.1	There is one Certification(s) and Seal(s) sub-section with a code of 3852212 and a displayName of "Certification(s) and Seal(s)".
3.10.2.0.2	Certification(s) and Seal(s) sub-section <title> must match the displayName.
3.10.2.1.1	There is zero to many Certification(s) and Seal(s) captured as code and displayName under <approval>.
3.10.2.1.2	If there is a certification and/or seal then there is text associated with the <approval>.
3.10.2.1.3	Certification(s) and Seal(s) codeSystem is 2.16.840.1.113883.6.275.1.
3.10.2.1.4	Certification(s) and Seal(s) displayName must match the code.

Figure 45: Marketing/ Advertising Claims Section XML Code Snippet

```
<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>
```

3.11 Additional Documentation and Labeling

3.11.0 Section in General

This label section provides an explanation for any additional documents or labeling associated with the registration that is uploaded as a Portable Document Format (PDF) document. If 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. If this section applies to a product, enter the appropriate text in this section text area. If this section does not apply to a product, leave the section text area blank.

- 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 non-permanently affixed to the product; 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.

- Reference: LRM Chapter 18.

Entry Type: PDF document upload from a user's local machine. Document uploads are saved to the 'Attachment' folder in the ZIP file.

Validation Procedures

ID Numbers	Validation Error Messages
3.11.0.0.1	There is one Additional Documentation and Labeling section with a code of 3144228 and a displayName of "Additional Documentation and Labeling".
3.11.0.0.2	Additional Documentation and Labeling section <title> must match the displayName.
3.11.0.0.3	There is zero to many document or label attachment references in the Additional Documentation and Labeling section.
3.11.0.0.4	Additional Documentation and Labeling attachments must have a "text" element with mediaType and "reference".
3.11.0.0.5	Additional Documentation and Labeling "reference" value must be the same as the valid filename of the respective attachment.
3.11.0.0.6	Additional Documentation and Labeling filename extension must match the mediaType ".pdf" or ".PDF".

Figure 46: Additional Documentation and Labeling Section 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>
```

4 Use Index

The goal of a 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. This is accomplished by translating narrative use patterns in the Product Labeling document and capturing them as combinations of discrete, predefined picklist terms and value entries. A Use Index can then be used as a tool to review and assess a Pesticide Product Label registration.

This document captures data as terms from a picklist, 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 sub-section. 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 to aid the user select the correct term when filling out a Use Index document. 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. Please periodically refer to the SmartLabel website for the most current listing of vocabularies and definitions as new terms will be added on a semi-regular basis.

4.1 Use Index SPL Header

4.1.0 Section in General

This section provides basic information for the identity of a Use Index document, its type, title, date, and versioning as a member of a document set. This information is captured in the Document Information section of the application and stored as part of the Use Index XML schema. See above **Section 1.2 Document Information** for additional information.

4.1.1 Document Type

This is the header name of the SmartLabel document containing data on the general subject matter of a label; i.e., Use Index.

Entry type: "Document type" picklist selection.

Validation Procedures:

ID Numbers	Validation Error Messages
4.1.1.0.1	There is one Use Index "Document Type" with a code of 3810133 and a displayName of "Use Index".
4.1.1.0.2	Use Index code comes from EPA's Document Type list.
4.1.1.0.3	Use Index codeSystem is 2.16.840.1.113883.6.275.1.
4.1.1.0.4	Use Index displayName matches the code.
4.1.1.0.5	If a document with the same set id was previously submitted then this document and the previous document are of the same type.

Figure 47: Use Index Document 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}"/>
```

4.1.2 Author Information

This provides basic information about the business responsible for the registered pesticide product, including the **Company Name** and **EPA Company Number**. See above **Section 1.2 Document Information (Package Information Section)** for additional information.

4.1.2.1 Company Name

Identifies the name of the organization registering the pesticide product using the **Company Name** registered with EPA. It is associated with the **EPA Company Number** and is populated from the CDX account of the user who created the SmartLabel document. See above **Section 1.2 Document Information (Package Information Section)** for additional information.

Entry type: Text.

Validation Procedures:

ID Numbers	Validation Error Messages
4.1.2.1.1	There is one Company Name (author) captured as <name> under <representedOrganization>.
4.1.2.1.2	Only <id> and <name> should be present under <representedOrganization>.
4.1.2.1.3	Company Name matches the name in the EPA Company Number list.

4.1.2.2 EPA Company Number

Identifies the organization associated with a pesticide product using a registered **EPA Company Number**. This identifier has a root of 2.16.840.1.113883.6.275.1 and extension. It is associated with the **Company Name** and is populated from the CDX account of the user who created the SmartLabel document. See above **Section 1.2 Document Information (Package Information Section)** for additional information.

Entry type: Value.

Validation Procedures:

ID Numbers	Validation Error Messages
4.1.2.2.1	There is one EPA Company Number captured as <id extension> under <representedOrganization>.

Figure 48: Author Information 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>
                       </assignedEntity>
                       </author>
```

4.2 Use Index SPL Body

4.2.0 Section in General

The body of a Use Index document includes structured text (e.g., Company Name), structured values (e.g., Percent Active Ingredient), and/or specific data elements from pick-lists (e.g., Use Site Locations).

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

Refer to **Section 2.2 HL7 SPL Body** of this document for specific information about how each structured XML section is coded.

Validation Procedures:

ID Numbers	Validation Error Messages
4.2.0.0.1	Section codes must come from the list "Use Index Section Names".
4.2.0.0.2	Use Index codeSystem is 2.16.840.1.113883.6.275.1.
4.2.0.0.3	Use Index displayName must match the code.
4.2.0.0.4	Use Index <title> and displayName must match.

Figure 49: Document Information 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>
      ...
```

4.2.1 Use Index Sections

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

- **Product Level** describes the registration and the restrictions/limitations that apply to all use sites and methods of application.
  - **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 user 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 a Use Index document contain text or narrative. A skeletal XML snippet is shown below.

Validation Procedures:

ID Numbers	Validation Error Messages
4.2.1.0.1	There is one "Product Level" section per Use Index document.
4.2.1.0.2	There is one or more "Site Level" section(s) per Use Index document.
4.2.1.0.3	There is one or more "Scenario Level" section(s) per Site Level section.

Figure 50: Use Index Sections XML Code Snippets

```
<?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"
                  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>
```

Figure 51: Use Index Sections XML Code Snippets (Continued)

```
<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>
```

4.3 Product Level

4.3.0 Section in General

The Product Level section is a header section that contains the Product Identification and Product Level Use Restrictions/Limitations sub-sections. Information entered in the Product Level sub-sections applies to all Use Sites and Scenarios.

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.0.0.1	There is one "Product Level" section.
4.3.0.0.2	Product Level section <title> and displayName must match.
4.3.0.0.3	Product Level section link is optional.
4.3.0.0.4	If the Product Level section link is provided then the section link is a unique string within the Use Index document.
4.3.0.0.5	Product Level section id is a unique UUID within the Use Index document.

Figure 52: Product Level Section 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>
```

4.3.1 Product Identification

This sub-section identifies the product and is used to link a Use Index document with a Pesticide Product 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:

ID Numbers	Validation Error Messages
4.3.1.0.1	There is one "Product Identification" section with code 3810085.
4.3.1.0.2	Product Identification section <title> and displayName must match.
4.3.1.0.3	Product Identification section link is optional.
4.3.1.0.4	If Product Identification section link is provided then the section link is a unique string within the Use Index document.
4.3.1.0.5	Product Identification <section ID> is a unique UUID within the Use Index document.

Figure 53: Product Identification 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>
```

Figure 54: Product Number XML Code Snippet

```
    <title>Product Identification</title>
    <subject>
      <manufacturedProduct>
        <manufacturedProduct>
          <!-- Product Number -->
          <code code="{Product Number}""/>
```

4.3.1.1 Product Number

This is a unique number assigned to a product by EPA. This number is combined with the EPA Company Number to form a unique identifier, known as the EPA Registration Number, for each registered pesticide product. While this number exists here per the Use Index XML schema, it is captured with the Package Information in the Document Information section of the application; Refer to **Section 1.2 Document Information (Package Information Section)** above for more information.

Entry type: Numeric text.

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.1.1.1	Product Number is required and cannot be null.
4.3.1.1.2	Product Number is assigned to the pesticide product by EPA and is part of the Registration Number.

4.3.1.2 Active Ingredients

Identifies and characterizes the active ingredients contained in a product captured as EPA Registry Name and Systematic Name 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).

- **Percent Active Ingredient** is the amount of active ingredient per the total amount of the formulated product.
- **Factoring Term Ingredient** optionally identifies ingredients of certain types of chemicals that theoretically could be converted back to the corresponding or "parent" active ingredient.
- **Percent Factoring Term** is 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.
- Each Active Ingredient can contain zero or one Factoring Term Ingredients.

Entry type: Picklist selection and value.

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.1.2.1	There is at least one or more Active Ingredient(s) with name and code provided under <ingredientSubstance>.
4.3.1.2.2	There is one Percent Active Ingredient per Active Ingredient with a unit code of 3627136 and a displayName of "%".
4.3.1.2.3	Percent Active Ingredient <value> is a number.
4.3.1.2.4	There is zero or one Factoring Term Ingredient per Active Ingredient with name and code provided under <activeMoiety>.
4.3.1.2.5	There is one Percent Factoring Term per Factoring Term Ingredient with a unit code of 3627136 and a displayName of "%".
3.4.1.1.6	Percent Factoring Term value is a number.

Figure 55: Active Ingredient and Percent Factoring Term XML Code Snippet

```
<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>
          <name use="OR">EPA Registry 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>
```

4.3.1.3 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:

ID Numbers	Validation Error Messages
4.3.1.3.1	Product Density is optional.
4.3.1.3.2	Product Density numerator value is a number.
4.3.1.3.3	Product Density denominator value is a number.
4.3.1.3.4	Product Density numerator units must be "pound".
4.3.1.3.5	Product Density denominator units must be "gallon".

Figure 56: Product Density 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>
```

4.3.1.4 Mass Product per Miscellaneous Application

The Mass Product per Miscellaneous Application 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 Version 3.xlsx** for a complete listing of Miscellaneous Application Units.

Entry type: Value unit, per value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.1.4.1	Mass Product per Miscellaneous Application is required if "Miscellaneous Application Units" are used in any of the rate sections at the Site or Scenario level(s).
4.3.1.4.2	Mass Product per Miscellaneous Application numerator value is a number.
4.3.1.4.3	Mass Product per Miscellaneous Application denominator value is a number.
4.3.1.4.4	Mass Product per Miscellaneous Application numerator units must be "Standard Weight/Mass".
4.3.1.4.5	Mass Product per Miscellaneous Application denominator units must be "Miscellaneous Application".

Figure 57: Mass Product per Miscellaneous Application XML Code Snippet

```
<title>Product Identification</title>
<subject>
  <manufacturedProduct>
    <!-- other elements -->
    <!-- Mass Product per Miscellaneous Application -->
    <subjectOf>
      <characteristic>
        <code code="1005311" codeSystem="2.16.840.1.113883.6.275.1"
            displayName="Mass Product per Miscellaneous Application "/>
        <value xsi:type="RTO_PQ_PQ">
          <numerator xsi:type="PQ" nullFlavor="OTH">
            <translation value="{Mass Product}"
                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>
```

4.3.2 Product Level Use Restrictions/Limitations

Identifies Product Level Restrictions/Limitations, which are applicable to all use sites and 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 data element blank indicates that the respective restriction does not apply at this level.

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.2.0.1	There is one "Product Level Use Restrictions/Limitations" section with code 3810086.
4.3.2.0.2	Product Level Use Restrictions/Limitations section <title> and displayName must match.
4.3.2.0.3	Product Level Use Restrictions/Limitations section link is optional.
4.3.2.0.4	If Product Level Use Restrictions/Limitations section link is provided then the section link is a unique string within the Use Index document.
4.3.2.0.5	Product Level Use Restrictions/Limitations section id is a unique UUID within the Use Index document.

Figure 58: : Product Level Use Restrictions/Limitations XML Code Snippet

```
<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>
```

4.3.2.1 Geographic Area(s) 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 of the product are not restricted to any particular geographic area, enter "United States". If application is not allowed in a particular area, enter all areas except the prohibited area.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.2.1.1	There is at least one or more Geographic Areas per Scenario. A Scenario is considered to have a Geographic Area if it is provided at the Product, Site, or Scenario Level.
4.3.2.1.2	If Geographic Area is provided at the Site or Scenario Level, then it should not also provided at the Product Level.
4.3.2.1.3	Geographic Area has a code of 1005202 and a displayName of "Geographic Area".
4.3.2.1.4	Geographic Area displayName must match the code.
4.3.2.1.5	If there is Geographic Area listed then there must be a <value> element with code and displayName.
4.3.2.1.6	Geographic Area <value> code and displayName must come from the list "Geographic Area".
4.3.2.1.7	Geographic Area <value> displayName must match the code.

Figure 59: Geographic Area 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>
```

4.3.2.2 Use Site Food Relationship

Identifies if applications 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 levels for each method to establish whether crops may be used as food or feed (including Bearing), or may not be used as food or feed (including Non-Bearing/Dormant, Grown for Seed). If the product labeling for non-agricultural sites explicitly prohibits applications that may contact food or feed, then "Non-Food/Non-Feed Stream" should be entered.

See definitions in the **SmartLabel Vocabulary Guide Version 3.xlsx** for further guidance.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.2.2.1	There is one Use Site Food Relationship per Scenario. A Scenario is considered to have a Use Site Food Relationship if it is provided at the Product, Site, or Scenario Level.
4.3.2.2.2	If Use Site Food Relationship is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.2.3	Use Site Food Relationship has a code of 1005021 and a displayName of "Use Site Food Relationship".
4.3.2.2.4	Use Site Food Relationship displayName must match the code.
4.3.2.2.5	If there is Use Site Food Relationship listed then there must be a <value> element with code and displayName.
4.3.2.2.6	Use Site Food Relationship <value> code and displayName must come from the list "Use Site Food Relationship".
4.3.2.2.7	Use Site Food Relationship <value> displayName must match the code.

Figure 60: Food Site Relationship 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>
```

4.3.2.3 Maximum A.I. 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. 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:

ID Numbers	Validation Error Messages
4.3.2.3.1	There is zero or one "Maximum AI Rate Across Products per Time".
4.3.2.3.2	If Maximum AI Rate Across Products per Time is provided at the Site or Scenario Level, then it should not also provided at the Product Level.
4.3.2.3.3	Maximum AI Rate Across Products per Time numerator value is a number.
4.3.2.3.4	Maximum AI Rate Across Products per Time denominator value is a number.
4.3.2.3.5	Maximum AI Rate Across Products per Time numerator units must be one of the following: "Standard Weight/Mass", "Standard Volume/Capacity", "Miscellaneous Application Unit", "Concentration", "Non-Standard Volume/Capacity".
4.3.2.3.6	Maximum AI Rate Across Products per Time denominator units must be one of the following: "Standard Area", "Standard Length", "Standard Weight/Mass", "Standard Volume/Capacity", "Time", "Non-Standard Volume/Capacity", "Non-standard - Target (with area rate limit)", "Non-Standard Weight/Mass", "Miscellaneous – Target".
4.3.2.3.7	Maximum AI Rate Across Products per Time <methodCode> is from the list "Application Rate Measurement Period".
4.3.2.3.8	If there is a Maximum AI Rate Across Products per Time numerator value then there must also be a denominator value.

Figure 61: Maximum A.I. Rate Across Products 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>
```

4.3.2.4 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:

ID Numbers	Validation Error Messages
4.3.2.4.1	There is zero or one "Rotational Crop" requirements.
4.3.2.4.2	If Rotational Crop is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.

Figure 62: Rotational Crop 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>
```

4.3.2.5 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 Restriction, by definition, indicates all other applicators not identified are restricted from using the product.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.2.5.1	There is zero to many "Applicator Class Restrictions".
4.3.2.5.2	If Applicator Class Restrictions is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.5.3	Applicator Class Restrictions has a code of 1004442 and a displayName of "Applicator Class Restrictions".
4.3.2.5.4	Applicator Class Restrictions displayName must match the code.
4.3.2.5.5	If there is Applicator Class Restrictions listed then there must be a <value> element with code and displayName.
4.3.2.5.6	Applicator Class Restrictions <value> code and displayName must come from the list "Applicator Class Restrictions".
4.3.2.5.7	Applicator Class Restrictions <value> displayName must match the code.

Figure 63: Applicator Class Restrictions 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>
```

4.3.2.6 PPE/Engineering Controls (+)

This indicates the PPE and/or engineering controls 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: "*PPE/Engineering Control*" picklist selection.

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.2.6.1	There is zero to many "PPE/Engineering Controls" requirements.
4.3.2.6.2	If PPE/Engineering Controls is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.6.3	Personal Protection Equipment (PPE)/Engineering Controls has a code of 1005024 and a displayName of "PPE/Engineering Controls".
4.3.2.6.4	PPE/Engineering Controls displayName must match the code.
4.3.2.6.5	If there is PPE/Engineering Controls listed then there must be a <value> element with code and displayName.
4.3.2.6.6	PPE/Engineering Controls <value> code and displayName must come from the list "PPE/Engineering Controls".
4.3.2.6.7	PPE/Engineering Controls <value> displayName must match the code.

Figure 64: PPE/Engineering Control XML Code Snippet

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
  <substanceAdministration>
    <componentOf>
      <protocol>
            <!-- other elements -->
        <!-- (0..*) PPE/Engineering Controls -->
        <component>
          <requirement>
            <code code="1005024" codeSystem="2.16.840.1.113883.6.275.1"
                displayName="PPE/Engineering Controls">
              <qualifier xsi:type="CR">
                <value code="{PPE/Engineering Controls Code}"
                     codeSystem="2.16.840.1.113883.6.275.1"
                     displayName="{PPE/Engineering Controls DisplayName}"/>
              </qualifier>
            </code>
          </requirement>
        </component>
```

4.3.2.7 Re-Entry Interval (REI)

Identifies the minimum period of time after a pesticide application when entry into the treated area is restricted; i.e., minimum period of time before worker re-entry. It includes WPS and non-WPS re-entry intervals.

Entry type: Value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.2.7.1	There is zero to one "Re-Entry Interval" requirements.
4.3.2.7.2	If Re-Entry Interval is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.7.3	Re-Entry Interval restriction occurs after application. (<sequenceNumber> value must be "3".)
4.3.2.7.4	Re-Entry Interval - Time value is a number.
4.3.2.7.5	Re-Entry Interval - Units must be units of time.

Figure 65: Re-Entry Interval XML Code Snippet

```
<title>Product Level Use Restrictions/Limitations</title>
<subject2>
  <substanceAdministration>
    <componentOf>
      <protocol>
            <!-- other elements -->
        <!-- (0..1) Re-Entry Interval-->
        <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>
```

4.3.2.8 Minimum Retreatment Interval (MRI)

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

Entry type: Value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.2.8.1	There is zero to one "Minimum Retreatment Interval" requirements.
4.3.2.8.2	If Minimum Retreatment Interval is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.8.3	Minimum Retreatment Interval is **required** if more than one application is allowed or if the single application rate is not equal to the crop cycle/yearly rate.
4.3.2.8.4	Minimum Retreatment Interval restriction occurs after application. (<sequenceNumber> value must be "3".)
4.3.2.8.5	Minimum Retreatment Interval - Time value is a number.
4.3.2.8.6	Minimum Retreatment Interval - Units must be units of time.

Figure 66: MRI 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>
```

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.2.9.1	There is zero to many "Pre-Harvest Interval Restrictions" requirements.
4.3.2.9.2	If Pre-Harvest Interval Restrictions is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.9.3	Pre-Harvest Interval Restrictions occur after application. (<sequenceNumber> value must be "3".)

ID Numbers	Validation Error Messages
4.3.2.9.4	Pre-Harvest Interval Restrictions has a code of 1005028 and a displayName of “PHI Category”.
4.3.2.9.5	Pre-Harvest Interval Restrictions displayName must match the code.
4.3.2.9.6	If there is Pre-Harvest Interval Restrictions listed then there must be a <value> element with code and displayName.
4.3.2.9.7	Pre-Harvest Interval Restrictions <value> code and displayName must come from the list "PHI Category".
4.3.2.9.8	Pre-Harvest Interval Restrictions <value> displayName must match the code.
4.3.2.9.9	Pre-Harvest Interval Restrictions - Time value is a number.
4.3.2.9.10	Pre-Harvest Interval Restrictions - Units must be units of time.

Figure 67: PHI 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>
```

4.3.2.10 Pre-Grazing/Pre-Feeding Interval Restrictions (PGI) (+)

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: “*PGI Category*” (Pre-Grazing/Pre-Feeding Interval) picklist selection, and value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.2.10.1	There is zero to many "Pre-Grazing/Pre-Feeding Interval Restrictions" requirements.

ID Numbers	Validation Error Messages
4.3.2.10.2	If Pre-Grazing/Pre-Feeding Interval Restrictions is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.10.3	Pre-Grazing/Pre-Feeding Interval Restrictions occurs after application. (<sequenceNumber> value must be “3”.)
4.3.2.10.4	Pre-Grazing/Pre-Feeding Interval Restrictions has a code of 1005026 and a displayName of “PGI Category”.
4.3.2.10.5	Pre-Grazing/Pre-Feeding Interval Restrictions displayName must match the code.
4.3.2.10.6	If there is Pre-Grazing/Pre-Feeding Interval Restrictions listed then there must be a <value> element with code and displayName.
4.3.2.10.7	Pre-Grazing/Pre-Feeding Interval Restrictions <value> code and displayName must come from the list "PGI Category".
4.3.2.10.8	Pre-Grazing/Pre-Feeding Interval Restrictions <value> displayName must match the code.
4.3.2.10.9	There is zero or one animal “Weight” or “Age” per Pre-Grazing/Pre-Feeding Interval Restriction.
4.3.2.10.10	Pre-Grazing/Pre-Feeding Interval Restrictions animal “Weight” value is a number.
4.3.2.10.11	Pre-Grazing/Pre-Feeding Interval Restrictions animal “Age” value is a number.
4.3.2.10.12	There is zero or one Pre-Grazing/Pre-Feeding Interval Restrictions - Time per Pre-Grazing/Pre-Feeding Interval Restriction.
4.3.2.10.13	Pre-Grazing/Pre-Feeding Interval Restrictions - Time value is a number.
4.3.2.10.14	Pre-Grazing/Pre-Feeding Interval Restrictions - Units must be units of time or weight, respectively.

Figure 68: Pre-Grazing/Pre-Feeding Interval XML Code Snippet

```
<componentOf>
  <protocol>
   <!-- other elements -->
   <!-- (0..*) PGI -->
   <component>
    <!-- after application -->
    <sequenceNumber value="3"/>
    <!-- wait some period of time -->
    <pauseQuantity xsi:type="PQ" nullFlavor="OTH">
     <translation value="{“Interval Time”}"
                  displayName="{“Unit of Measure Display name”}"
                  code="{“UoM Code”}"
                  codeSystem="2.16.840.1.113883.6.275.1"/>
    </pauseQuantity>
    <!-- conduct observation -->
    <monitoringObservation>
     <code code="1005026"
           codeSystem="2.16.840.1.113883.6.275.1"
           displayName=" PGI Category "/>
     <precondition>
      <observationCriterion>
       <code code="3608438"
             codeSystem="2.16.840.1.113883.6.275.1"
             displayName="Animals weighing less than ___"/>
       <!-- Animal Weight / Age -->
       <value xsi:type="PQ" nullFlavor="OTH">
        <translation value="5"
                     displayName="pound"
                     code="3627071"
                     codeSystem="2.16.840.1.113883.6.275.1"/>
       </value>
      </observationCriterion>
     </precondition>
    </monitoringObservation>
   </component>
  </protocol>
</componentOf>
```

4.3.2.11 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:

ID Numbers	Validation Error Messages
4.3.2.11.1	There is zero to many "Pre-Slaughter Interval Restrictions" requirements.
4.3.2.11.2	If Pre-Slaughter Interval Restrictions is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.11.3	Pre-Slaughter Interval Restrictions occur after application. (<sequenceNumber> value must be “3”.)
4.3.2.11.4	Pre-Slaughter Interval Restrictions has a code of 1005027 and a displayName of “PSI Category”.
4.3.2.11.5	Pre-Slaughter Interval Restrictions displayName must match the code.

ID Numbers	Validation Error Messages
4.3.2.11.6	If there is Pre-Slaughter Interval Restrictions listed then there must be a <value> element with code and displayName.
4.3.2.11.7	Pre-Slaughter Interval Restrictions <value> code and displayName must come from the list "PSI Category".
4.3.2.11.8	Pre-Slaughter Interval Restrictions <value> displayName must match the code.
4.3.2.11.9	There is zero or one Pre-Slaughter Interval Restrictions - Time per Pre-Slaughter Interval Restriction.
4.3.2.11.10	Pre-Slaughter Interval Restrictions - Time value is a number.
4.3.2.11.11	Pre-Slaughter Interval Restrictions - Units must be units of time.

Figure 69: Pre-Slaughter Interval 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>
```

4.3.2.12 Buffered Area(s) (+)

Identifies the minimum distance that is required between the area where a pesticide 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:

ID Numbers	Validation Error Messages
4.3.2.12.1	There is zero to many "Buffered Area(s)" preconditions.
4.3.2.12.2	If Buffered Area(s) is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.12.3	Buffered Area(s) checkPoint code is "T".

ID Numbers	Validation Error Messages
4.3.2.12.4	Buffered Area(s) has a code of 1004980 and a displayName of “Buffered Area”.
4.3.2.12.5	Buffered Area(s) displayName must match the code.
4.3.2.12.6	If there is Buffered Area(s) listed then there must be a <value> element with code and displayName.
4.3.2.12.7	Buffered Area(s) <value> code and displayName must come from the list "Buffered Area".
4.3.2.12.8	Buffered Area(s) <value> displayName must match the code.
4.3.2.12.9	Buffered Area(s) - Distance value is a number.
4.3.2.12.10	Buffered Area(s) - Units must be "Standard Length" units.

Figure 70: Buffered Area 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>
```

4.3.2.13 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:

ID Numbers	Validation Error Messages
4.3.2.13.1	There is zero or one "Maximum Release Height" preconditions.
4.3.2.13.2	If Max Release Height is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.13.3	Max Release Height checkPoint code is "T".
4.3.2.13.4	Max Release Height - Height value is a number.
4.3.2.13.5	Max Release Height - Units must be "Standard Length" units.

Figure 71: Maximum Release Height 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>
```

4.3.2.14 Max Wind Speed

Identifies the maximum wind speed allowed during application.

Entry type: Value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.2.14.1	There is zero or one "Maximum Wind Speed" preconditions.
4.3.2.14.2	If Max Wind Speed is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.14.3	Max Wind Speed checkPoint code is "T".
4.3.2.14.4	Max Wind Speed - Speed value is a number.
4.3.2.14.5	Max Wind Speed - Units must be units of speed.

Figure 72: Maximum Wind Speed 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>
```

4.3.2.15 Application Temperature

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

Entry type: Value unit, value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.2.15.1	There is zero or one "Application Temperature" preconditions.
4.3.2.15.2	If Application Temperature is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.15.3	Application Temperature checkPoint code is "B".
4.3.2.15.4	Application Temperature - Min Temp value is a number.
4.3.2.15.5	Application Temperature - Max Temp value is a number.
4.3.2.15.6	Application Temperature - Units (Min Temp/Max Temp) must be temperature units.
4.3.2.15.7	Application Temperature - Units must match when both limits are provided.
4.3.2.15.8	"Min Temp" and "Max Temp" do not need to be provided together.

Figure 73: Application Temperature 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>
```

4.3.2.16 American Society of Agricultural and Biological Engineers (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:

ID Numbers	Validation Error Messages
4.3.2.16.1	There is zero to many "ASABE Droplet Size" requirements.
4.3.2.16.2	If ASABE Droplet Size is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.16.3	ASABE Droplet Size is **required** when Application Type = "broadcast", Form as Applied = "liquid formations" and/or Application Equipment = "Aerial"' or "Groundboom".
4.3.2.16.4	ASABE Droplet Size has a code of 1004962 and a displayName of "ASABE Droplet Size".
4.3.2.16.5	ASABE Droplet Size displayName must match the code.
4.3.2.16.6	If there is ASABE Droplet Size listed then there must be a <value> element with code and displayName.
4.3.2.16.7	ASABE Droplet Size <value> code and displayName must come from the list "ASABE Droplet Size".

ID Numbers	Validation Error Messages
4.3.2.16.8	ASABE Droplet Size <value> displayName must match the code.

Figure 74: ASABE Droplet Size XML Code Snippet

```
<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>
```

4.3.2.17 Soil Incorporation Depth and Time

Identifies the minimum soil incorporation depth that is required for the application, and the maximum amount of time that must pass before incorporation takes place. If soil incorporation occurs at the time of application, a time of "0" minutes should be entered.

Entry type: Value unit, value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.2.17.1	There is zero or one "Soil Incorporation Depth and Time" observations.
4.3.2.17.2	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.
4.3.2.17.3	Soil Incorporation Depth and Time restriction occurs after application. (<sequenceNumber> value must be "3".)
4.3.2.17.4	If soil incorporation occurs at the time of application then "Time" is "0" and "Units" are "minutes".
4.3.2.17.5	If there is a soil incorporation "Time" then there should also be a soil incorporation "Depth".
4.3.2.17.6	Soil Incorporation Depth and Time - Units must be units of time and "Standard Length", respectively.

Figure 75: Soil Incorporation Depth and Time 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>
```

4.3.2.18 Restricted Soil Type (+)

Identifies any soil type(s) to which the product should not be applied using the prescribed methods.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.2.18.1	There is zero to many "Restricted Soil Type(s)" preconditions.
4.3.2.18.2	If Restricted Soil Type(s) is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.18.3	Restricted Soil Type(s) checkPoint code is "B".

ID Numbers	Validation Error Messages
4.3.2.18.4	Restricted Soil Type(s) has a code of 1004961 and a displayName of “Soil Type”.
4.3.2.18.5	Restricted Soil Type(s) displayName must match the code.
4.3.2.18.6	If there is Restricted Soil Type(s) listed then there must be a <value> element with code and displayName.
4.3.2.18.7	Restricted Soil Type(s) <value> code and displayName must come from the list "Soil Type".
4.3.2.18.8	Restricted Soil Type(s) <value> displayName must match the code.

Figure 76: Restricted Soil Type 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>
```

4.3.2.19 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:

ID Numbers	Validation Error Messages
4.3.2.19.1	There is zero or one "Minimum Percent Soil Organic Matter" preconditions.
4.3.2.19.2	If Minimum Percent Soil Organic Matter is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.19.3	Minimum Percent Soil Organic Matter <checkPoint> code is "B".
4.3.2.19.4	Minimum Percent Soil Organic Matter - Value is a number.
4.3.2.19.5	Minimum Percent Soil Organic Matter has a unit code of 3627136 and a displayName of "%".

Figure 77: Minimum Percent Soil Organic Matter 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>
```

4.3.2.20 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:

ID Numbers	Validation Error Messages
4.3.2.20.1	There is zero or one "Minimum Age of Animal To Be Treated" preconditions.
4.3.2.20.2	If Minimum Age of Animal To Be Treated is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.20.3	Minimum Age of Animal To Be Treated <checkPoint> code is "B".
4.3.2.20.4	Minimum Age of Animal To Be Treated - Age value is a number.
4.3.2.20.5	Minimum Age of Animal To Be Treated - Units must be units of time.

Figure 78: Minimum Age of Animal To Be Treated 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>
```

4.3.2.21 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:

ID Numbers	Validation Error Messages
4.3.2.21.1	There is zero or one "Minimum Weight of Animal To Be Treated" preconditions.
4.3.2.21.2	If Minimum Weight of Animal To Be Treated is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.21.3	Minimum Weight of Animal To Be Treated <checkPoint> code is "B".
4.3.2.21.4	Minimum Weight of Animal To Be Treated - Weight value is a number.
4.3.2.21.5	Minimum Weight of Animal To Be Treated - Units must be "Standard Weight/Mass" units.

Figure 79: Minimum Weight of Animal To Be Treated 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>
```

4.3.2.22 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:

ID Numbers	Validation Error Messages
4.3.2.22.1	There is zero to many "Pollinator Protection Statement(s)" requirements.
4.3.2.22.2	If Pollinator Protection Statement(s) is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.22.3	Pollinator Protection Statement(s) has a code of 1005022 and a displayName of "Pollinator Protection Statements".
4.3.2.22.4	Pollinator Protection Statement(s) displayName must match the code.
4.3.2.22.5	If there is Pollinator Protection Statement(s) listed then there must be a <value> element with code and displayName.
4.3.2.22.6	Pollinator Protection Statement(s) <value> code and displayName must come from the list "Pollinator Protection Statements".
4.3.2.22.7	Pollinator Protection Statement(s) <value> displayName must match the code.

Figure 80: Pollinator Protection Statement 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>
```

4.3.2.23 Bulletins Live

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

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.2.23.1	There is zero or one "Bulletins Live" requirements.
4.3.2.23.2	If Bulletins Live is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.

Figure 81: Bulletins Live 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>
```

4.3.2.24 Applications to Water (+)

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

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.2.24.1	There is zero to many "Water Protection Statement(s)" requirements.
4.3.2.24.2	If Water Protection Statement(s) is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.24.3	Water Protection Statement(s) has a code of 1005023 and a displayName of "Water Protection Statements".
4.3.2.24.4	Water Protection Statement(s) displayName must match the code.
4.3.2.24.5	If there is Water Protection Statement(s) listed then there must be a <value> element with code and displayName.
4.3.2.24.6	Water Protection Statement(s) <value> code and displayName must come from the list "Water Protection Statements".
4.3.2.24.7	Water Protection Statement(s) <value> displayName must match the code.
4.3.2.24.8	Water Protection Statement(s) - Value is a number.
4.3.2.24.9	Water Protection Statement(s) - Units must be provided.

Figure 82: Water Protection Statement XML Code Snippet

```
<!-- (0..*) Applications to Water -->
 <component>
  <!-- after application -->
  <sequenceNumber value="3"/>
  <!-- conduct observation -->
  <monitoringObservation>
   <code code="1005023"
         codeSystem="2.16.840.1.113883.6.275.1"
         displayName="Water Protection Statement"/>
   <precondition>
    <observationCriterion>
     <code code="{Water Protection Statement Code}"
           codeSystem="2.16.840.1.113883.6.275.1"
           displayName="{Water Protection Statement}"/>
     <value xsi:type="PQ" nullFlavor="OTH">
      <translation code="{Unit Code}"
                   codeSystem="2.16.840.1.113883.6.275.1"
                   displayName="{Unit DisplayName}"
                   value="{Some Value}"/>
     </value>
    </observationCriterion>
   </precondition>
  </monitoringObservation>
 </component>
```

4.3.2.25 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 manufacturing appear on the label, then Secondary Manufacturing should be selected.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.3.2.25.1	There is zero or one "Secondary Manufacturing" requirements.
4.3.2.25.2	If Secondary Manufacturing is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.

Figure 83: Secondary Manufacturing 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>
```

4.3.2.26 Restricted Use Site Location(s) (+)

Identifies if applications are not permitted in specific Use Site Locations. Locations entered as restricted at the Product Level 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:

ID Numbers	Validation Error Messages
4.3.2.26.1	There is zero to many "Restricted Use Site Location(s)" preconditions.
4.3.2.26.2	If Restricted Use Site Location(s) is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.26.3	Restricted Use Site Location(s) <checkPoint> code is "B".
4.3.2.26.4	Restricted Use Site Location(s) has a code of 1004663 and a displayName of "Use Site Location".
4.3.2.26.5	Restricted Use Site Location(s) displayName must match the code.
4.3.2.26.6	If there is Restricted Use Site Location(s) listed then there must be a <value> element with code and displayName.

Figure 84: Restricted Use Site Location 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="Restricted Use Site Location"/>
            <value xsi:type="CD" code="{Restricted Use Site Location Code}"

codeSystem="2.16.840.1.113883.6.275.1"
                 displayName="{RestrictedUse Site Location DisplayName}"/>
            <!-- not the condition -->
            <valueNegationInd value="true"/>
          </observationCriterion>
        </precondition>
```

4.3.2.27 Restricted Application Target(s) (+)

Identifies if applications are not permitted to specific targets. Targets entered as restricted at the Product Level 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:

ID Numbers	Validation Error Messages
4.3.2.27.1	There is zero to many "Restricted Application Target(s)" preconditions.
4.3.2.27.2	If Restricted Application Target(s) is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.27.3	Restricted Application Target(s) <checkPoint> code is "B".
4.3.2.27.4	Restricted Application Target(s) has a code of 1004682 and a displayName of "Application Target".
4.3.2.27.5	Restricted Application Target(s) displayName must match the code.
4.3.2.27.6	If there is Restricted Application Target(s) listed then there must be a <value> element with code and displayName.
4.3.2.27.7	Restricted Application Target(s) <value> code and displayName must come from the list "Application Target".
4.3.2.27.8	Restricted Application Target(s) <value> displayName must match the code.

Figure 85: Restricted Application Target 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>
```

4.3.2.28 Restricted Application Type(s) (+)

Identifies if applications are not permitted using specific application types. Application types entered as restricted at the Product Level 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:

ID Numbers	Validation Error Messages
4.3.2.28.1	There is zero to many "Restricted Application Type(s)" preconditions.
4.3.2.28.2	If Restricted Application Type(s) is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.28.3	Restricted Application Type(s) <checkPoint> code is "B".
4.3.2.28.4	Restricted Application Type(s) has a code of 1004920 and a displayName of "Application Type".
4.3.2.28.5	Restricted Application Type(s) displayName must match the code.
4.3.2.28.6	If there is Restricted Application Type(s) listed then there must be a <value> element with code and displayName.
4.3.2.28.7	Restricted Application Type(s) <value> code and displayName must come from the list "Application Type".
4.3.2.28.8	Restricted Application Type(s) <value> displayName must match the code.

Figure 86: Restricted Application Type 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"
                displayName="{Application Type DisplayName}"/>
            <!-- not the condition -->
            <valueNegationInd value="true"/>
          </observationCriterion>
        </precondition>
```

4.3.2.29 Restricted Application Equipment (+)

Identifies if applications are not permitted using specific equipment. Equipment entered as restricted at the Product Level 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:

ID Numbers	Validation Error Messages
4.3.2.29.1	There is zero to many "Restricted Application Equipment" preconditions.
4.3.2.29.2	If Restricted Application Equipment is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.29.3	"Restricted Application Equipment" <checkPoint> code is "B".
4.3.2.29.4	Restricted Application Equipment has a code of 1004922 and a displayName of "Application Equipment".
4.3.2.29.5	Restricted Application Equipment displayName must match the code.
4.3.2.29.6	If there is Restricted Application Equipment listed then there must be a <value> element with code and displayName.
4.3.2.29.7	Restricted Application Equipment <value> code and displayName must come from the list "Application Equipment".
4.3.2.29.8	Restricted Application Equipment <value> displayName must match the code.

Figure 87: Restricted Application Equipment 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"/>
          </observationCriterion>
        </precondition>
```

4.3.2.30 Restricted Application Timing (+)

Identifies if applications are not permitted during specific timings (e.g., “Time of Day”, “Timing of Pest”, “Use Site Status”). Timings entered as restricted at the Product Level 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:

ID Numbers	Validation Error Messages
4.3.2.30.1	There is zero to many "Restricted Application Timing (Use Site Status)", "Restricted Application Timing (Time of Day)", and/or "Restricted Application Timing (Timing of Pest)" preconditions.
4.3.2.30.2	If Restricted Application Timing is provided at the Site or Scenario Level, then it should not also be provided at the Product Level.
4.3.2.30.3	Restricted Application Timing <checkpointCode> code is "B".
4.3.2.30.4	Restricted Application Timing (Time of Day) has a code of 1004921 and a displayName of “Application Timing (Time of Day)”.
4.3.2.30.5	Restricted Application Timing (Timing of Pest) has a code of 1005020 and a displayName of “Application Timing (Timing of Pest)”.
4.3.2.30.6	Restricted Application Timing (Use Site Status) has a code of 1004960 and a displayName of “Application Timing (Use Site Status)”.
4.3.2.30.7	Restricted Application Timing displayName must match the code.
4.3.2.30.8	If there is Restricted Application Timing listed then there must be a <value> element with code and displayName.
4.3.2.30.9	Restricted Application Timing (Time of Day) <value> code and displayName must come from the list "Application Timing (Time of Day)".
4.3.2.30.10	Restricted Application Timing (Timing of Pest) <value> code and displayName must come from the list "Application Timing (Timing of Pest)".

ID Numbers	Validation Error Messages
4.3.2.30.11	Restricted Application Timing (Use Site Status) <value> code and displayName must come from the list "Application Timing (Use Site Status)".
4.3.2.30.12	Restricted Application Timing <value> displayName must match the code.

Figure 88: Restricted Application Timing 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 -->
            <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>
```

4.4 Site Level (+)

4.4.0 Section in General

The Site Level section is a header section to contain the sub-sections defined herein and the Scenario Level sub-sections. The Site Level section can be cloned/repeated to create many site level sections within a Product Level section. Adding a new or cloning an existing Site Level section will add/clone all sub-sections contained within the respective Site Level.

Each site is defined as a place with the combination of Use Site Attributes (Use Sites and Use Site Locations) to which the product may 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 require 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 (Use Sites and Use Site Locations) may be listed under a single Site Level. Likewise, if a label has more complicated application instructions, then additional Sites Levels can be added to isolate caveats to the maximum use. This may also include Geographic Restrictions when rates differ based on geography. Before entering information to define a site, look across the product application instructions to determine if there are unique use 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. Conversely, if the parameters for all Use Sites and Use Site Locations remain unchanged for Site Yearly/Crop Cycle Rate and Site Level Restrictions/Limitations, then a single Site Level can be used to capture all the details. It is important to remember, however, that all combinations of selections must be permitted.

There may be one to many Site Level sections. Each Site Level section must have at least one scenario. Each Site Level section should contain parameters unique to the respective Use Site and Use Site Location combinations selected. For example:

- Site Level 1
    - Use Site Attributes
        - Use Site “A”
        - Use Site Location “a”
        - Use Site Location “b”
    - Use Site Yearly/Crop Cycle Rate “1”
    - Use Site Level Restrictions/Limitations “xxx”

- Site Level 2
    - Use Site Attributes
        - Use Site “B”
        - Use Site “C”
        - Use Site Location “a”
        - Use Site Location “c”
    - Use Site Yearly/Crop Cycle Rate “2”
    - Use Site Level Restrictions/Limitations “yyy”

Information entered in the Site Level subsections applies to all Scenarios associated with that Site Level.

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.0.0.1	There is at least one or more "Site Level" section(s) per Use Index document.
4.4.0.0.2	Site Level section <title> and displayName must match.
4.4.0.0.3	Site Level section link is optional.
4.4.0.0.4	If Site Level section link is provided then the section link is a unique string within the Use Index document.
4.4.0.0.5	Site Level <section ID> is a unique UUID within the Use Index> document.

Figure 89: Site Level Section 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>
```

4.4.1 Use Site Attributes

The Use Site Attributes section is a sub-section 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.

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.1.0.1	There is one "Use Site Attributes" sub-section per Site Level section.
4.4.1.0.2	Use Site Attributes section <title> and displayName must match.
4.4.1.0.3	Use Site Attributes section link is optional.
4.4.1.0.4	If Use Site Attributes section link is provided then the section link is a unique string within the Use Index document.
4.4.1.0.5	Use Site Attributes <section ID> is a unique UUID within the Use Index document.
4.4.1.0.6	Use Site Attributes section must have a code and displayName.

4.4.1.1 Use Site/Commodity (+)

Identifies the person, place, or thing being treated. 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 “Crop Use Sites” and “Non-Crop Use Sites” lists in the **SmartLabel Vocabulary Guide Version 3.xlsx** document for guidance.

Entry type: “*Use Site/Commodity*” picklist selection.

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.1.1.1	There is at least one to many "Use Site(s)/Commodities".
4.4.1.1.2	Use Site(s)/Commodities has a code of 3810088 and a displayName of "Use Site/Commodity".
4.4.1.1.3	Use Site(s)/Commodities displayName must match the code.
4.4.1.1.4	If there is Use Site(s)/Commodities listed then there must be a <value> element with code and displayName.
4.4.1.1.5	Use Site(s)/Commodities <value> code must come from the list "Registered Use Site" under codeSystem 2.16.840.1.113883.6.275.1.
4.4.1.1.6	Use Site(s)/Commodities <value> code must match the displayName.

4.4.1.2 Use Site Location(s) (+)

The Use Site Location gives a broad category-based description of where the person, place, or thing being treated (Use Site) can be found (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.

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.1.2.1	There is at least one to many "Use Site Location(s)".
4.4.1.2.2	Use Site Location(s) cannot be restricted in the Product Level section.
4.4.1.2.3	Use Site Location(s) code is from the list "Use Site Location".
4.4.1.2.4	Use Site Location(s) displayName must match the code.

Figure 90: Use Site Attributes 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>
```

4.4.2 Use Site Yearly/Crop Cycle Rate (+)

Use Site Yearly/Crop Cycle Rate is a sub-section of the Site Level section containing Maximum Number of Applications per Site per Time and Maximum Site Application Rate per Time.

Each Site Level must include either a Maximum Number of Applications per Site per Time, a Maximum Site Application Rate per Time, or both elements. If both Maximum Number of Applications per Site per Time and Maximum Site Application Rate per Time 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 in the Maximum Number of Crop Cycles per Year field at the Scenario Level; see **Section 4.5.1.9 Maximum Number of Crop Cycles per Year** below.

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.2.0.1	There is one "Use Site Yearly/Crop Cycle Rate" sub-section per Site Level section.
4.4.2.0.2	Use Site Yearly/Crop Cycle Rate section <title> and displayName must match.
4.4.2.0.3	Use Site Yearly/Crop Cycle Rate section link is optional.
4.4.2.0.4	If Use Site Yearly/Crop Cycle Rate section link is provided then the section link is a unique string within the Use Index document.

ID Numbers	Validation Error Messages
4.4.2.0.5	Use Site Yearly/Crop Cycle Rate <section ID> is a unique UUID within the Use Index document.

4.4.2.1 Maximum Number of Applications per Site per Time

Identifies the maximum number of applications that can be applied per year or per crop cycle to the use site from all scenarios combined.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.2.1.1	At least one, "Maximum Number of Applications per Site per Time" or "Maximum Site Application Rate per Time", must be provided per Site Level section.
4.4.2.1.2	Maximum Number of Applications per Site per Time - Number value is a number.
4.4.2.1.3	Maximum Number of Applications per Site per Time - Per Time is "Year" or "Crop Cycle".
4.4.2.1.4	Maximum Number of Applications per Site per Time value cannot exceed the value for Product Level Use Restrictions/Limitations.
4.4.2.1.5	Maximum Number of Applications per Site per Time <methodCode> is from the list "Application Rate Measurement Period".

4.4.2.2 Maximum Site Application Rate per Time

Identifies the maximum quantity of a product that can be applied per year or per crop cycle to the use site from all scenarios combined.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.2.2.1	Maximum Site Application Rate per Time numerator value is a number.
4.4.2.2.2	Maximum Site Application Rate per Time denominator value is a number.
4.4.2.2.3	Maximum Site Application Rate per Time numerator units must be one of the following: "Standard Weight/Mass"; " Standard Volume/Capacity"; "Miscellaneous Application Unit"; "Concentration"; "Non-Standard Volume/Capacity".
4.4.2.2.4	Maximum Site Application Rate per Time denominator units must be one of the following: "Standard Area"; "Standard Length"; "Standard Weight/Mass"; "Standard Volume/Capacity"; "Time"; "Non-Standard Volume/Capacity"; "Non-standard - Target (with acreage rate limit)"; "Non-Standard Weight/Mass"; "Miscellaneous – Target".
4.4.2.2.5	Maximum Site Application Rate per Time <methodCode> is from the list "Application Rate Measurement Period".
4.4.2.2.6	If there is a Maximum Site Application Rate per Time numerator value then there must also be a denominator value.

Figure 91: Use Site Yearly Rate 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">
                     <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>
```

4.4.3 Use Site Level Restrictions/Limitations (+)

Identifies Use Site Level Restrictions/Limitations that are applicable to all scenarios for a respective site. If a restriction/limitation differs between scenarios of a given site, it should be entered only at the scenario level for that site. Restriction/limitation information cannot be entered at multiple levels. Restrictions/limitations should only be recorded in a 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 data element blank indicates that the respective restriction does not apply at this level.

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.3.0.1	There is one "Use Site Level Restrictions/Limitations" section per Site Level section.
4.4.3.0.2	Use Site Level Restrictions/Limitations section <title> and displayName must match.
4.4.3.0.3	Use Site Level Restrictions/Limitations section link is optional.
4.4.3.0.4	If Use Site Level Restrictions/Limitations section link is provided then the section link is a unique string within the Use Index document.
4.4.3.0.5	Use Site Level Restrictions/Limitations <section ID> is a unique UUID within the Use Index document.

Figure 92: Use Site Level Restrictions/Limitations 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>
```

4.4.3.1 Geographic Area(s) 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 to a specific site are not restricted to any particular geographic area, enter "United States". If application is not allowed in a particular area, enter all areas except the prohibited area.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.3.1.1	There is at least one "Geographic Area" per Scenario. The Scenario is considered to have a Geographic Area if it is provided at the Product, Site, or Scenario Level.
4.4.3.1.2	If Geographic Area is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.1.3	Geographic Area has a code of 1005202 and a displayName of "Geographic Area".
4.4.3.1.4	Geographic Area displayName must match the code.
4.4.3.1.5	If there is Geographic Area listed then there must be a <value> element with code and displayName.
4.4.3.1.6	Geographic Area <value> code and displayName must come from the list "Geographic Area".
4.4.3.1.7	Geographic Area <value> displayName must match the code.

Figure 93: Geographic Area 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>
```

4.4.3.2 Use Site Food 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 levels for each method to establish whether crops may be used as food/feed or may not be used as food/feed. If the product labeling for non-agricultural sites explicitly prohibits applications that may contact food or feed, then "Non-Food/Non-Feed Stream" should be entered.

See definitions in the **SmartLabel Vocabulary Guide Version 3.xlsx** for further guidance.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.3.2.1	There is one "Use Site Food Relationship" per Scenario. A Scenario is considered to have a Use Site Food Relationship if it is provided at the Product, Site, or Scenario Level.
4.4.3.2.2	If Use Site Food Relationship is provided at the Product or Scenario Level, then it should not also be provided at the Site Level.
4.4.3.2.3	Use Site Food Relationship has a code of 1005021 and a displayName of "Use Site Food Relationship".
4.4.3.2.4	Use Site Food Relationship displayName must match the code.
4.4.3.2.5	If there is Use Site Food Relationship listed then there must be a <value> element with code and displayName.
4.4.3.2.6	Use Site Food Relationship <value> code and displayName must come from the list "Use Site Food Relationship".
4.4.3.2.7	Use Site Food Relationship <value> displayName must match the code.

Figure 94: Food Site Relationship 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>
```

4.4.3.3 Maximum Active Ingredient Rate Across Products per Time

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. 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:

ID Numbers	Validation Error Messages
4.4.3.3.1	There is zero or one "Maximum AI Rate Across Products per Time".
4.4.3.3.2	If Maximum AI Rate Across Products per Time is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.3.3	Maximum AI Rate Across Products per Time numerator value is a number.
4.4.3.3.4	Maximum AI Rate Across Products per Time denominator value is a number.
4.4.3.3.5	Maximum AI Rate Across Products per Time numerator units must be one of the following: "Standard Weight/Mass", "Standard Volume/Capacity", "Miscellaneous Application Unit", "Concentration", "Non-Standard Volume/Capacity".
4.4.3.3.6	Maximum AI Rate Across Products per Time denominator units must be one of the following: "Standard Area", "Standard Length", "Standard Weight/Mass", "Standard Volume/Capacity", "Time", "Non-Standard Volume/Capacity", "Non-standard - Target (with area rate limit)", "Non-Standard Weight/Mass", "Miscellaneous – Target".
4.4.3.3.7	Maximum AI Rate Across Products per Time <methodCode> is from the list "Application Rate Measurement Period".
4.4.3.3.8	If there is a Maximum AI Rate Across Products per Time numerator value then there must also be a denominator value.

Figure 95: Maxium AI Rate Across Products 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>
```

4.4.3.4 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:

ID Numbers	Validation Error Messages
4.4.3.4.1	There is zero or one "Rotational Crop" requirements.
4.4.3.4.2	If Rotational Crop is provided at the Product or Scenario Level, then it should not also provided at the Site Level.

Figure 96: Rotational Crop 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>
```

4.4.3.5 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 Restriction, by definition, indicates all other applicators not identified are restricted from using the product.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.3.5.1	There is zero to many "Applicator Class Restrictions".
4.4.3.5.2	If Applicator Class Restrictions is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.5.3	Applicator Class Restrictions has a code of 1004442 and a displayName of "Applicator Class Restrictions".
4.4.3.5.4	Applicator Class Restrictions displayName must match the code.
4.4.3.5.5	If there is Applicator Class Restrictions listed then there must be a <value> element with code and displayName.
4.4.3.5.6	Applicator Class Restrictions <value> code and displayName must come from the list "Applicator Class Restrictions".
4.4.3.5.7	Applicator Class Restrictions <value> displayName must match the code.

Figure 97: Applicator Class Restrictions 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>
```

4.4.3.6 PPE/Engineering Controls (+)

This indicates the PPE and/or engineering controls 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 Protection Equipment (PPE)/Engineering Control*" picklist selection.

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.3.6.1	There is zero to many "PPE/Engineering Controls" requirements.
4.4.3.6.2	If PPE/Engineering Controls is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.6.3	Personal Protection Equipment (PPE)/Engineering Controls has a code of 1005024 and a displayName of "PPE/Engineering Controls".
4.4.3.6.4	PPE/Engineering Controls displayName must match the code.
4.4.3.6.5	If there is PPE/Engineering Controls listed then there must be a <value> element with code and displayName.
4.4.3.6.6	PPE/Engineering Controls <value> code and displayName must come from the list "PPE/Engineering Controls".
4.4.3.6.7	PPE/Engineering Controls <value> displayName must match the code.

Figure 98: PPE/Engineering Control 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>
```

4.4.3.7 REI

Identifies the minimum period of time after a pesticide application when entry into the treated area is restricted; i.e., minimum period of time before worker re-entry. It includes WPS and non-WPS re-entry intervals.

Entry type: Value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.3.7.1	There is zero to one "Re-Entry Interval" requirements.
4.4.3.7.2	If Re-Entry Interval is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.7.3	Re-Entry Interval restriction occurs after application. (<sequenceNumber> value must be "3".)
4.4.3.7.4	Re-Entry Interval - Time value is a number.
4.4.3.7.5	Re-Entry Interval - Units must be units of time.

Figure 99: Re-Entry Interval 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>
```

4.4.3.8 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:

ID Numbers	Validation Error Messages
4.4.3.8.1	There is zero to one "Minimum Retreatment Interval" requirements.
4.4.3.8.2	If Minimum Retreatment Interval is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.8.3	Minimum Retreatment Interval is required if more than one application is allowed or if the single application rate is not equal to the crop cycle/yearly rate.
4.4.3.8.4	Minimum Retreatment Interval restriction occurs after application. (<sequenceNumber> value must be "3".)
4.4.3.8.5	Minimum Retreatment Interval - Time value is a number.
4.4.3.8.6	Minimum Retreatment Interval - Units must be units of time.

Figure 100: MRI 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>
```

4.4.3.9 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:

ID Numbers	Validation Error Messages
4.4.3.9.1	There is zero to many "Pre-Harvest Interval Restrictions" requirements.
4.4.3.9.2	If Pre-Harvest Interval Restrictions is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.9.3	Pre-Harvest Interval Restrictions occur after application. (<sequenceNumber> value must be "3".)
4.4.3.9.4	Pre-Harvest Interval Restrictions has a code of 1005028 and a displayName of "PHI Category".
4.4.3.9.5	Pre-Harvest Interval Restrictions displayName must match the code.
4.4.3.9.6	If there is Pre-Harvest Interval Restrictions listed then there must be a <value> element with code and displayName.
4.4.3.9.7	Pre-Harvest Interval Restrictions <value> code and displayName must come from the list "PHI Category".
4.4.3.9.8	Pre-Harvest Interval Restrictions <value> displayName must match the code.
4.4.3.9.9	Pre-Harvest Interval Restrictions - Time value is a number.
4.4.3.9.10	Pre-Harvest Interval Restrictions - Units must be units of time.

Figure 101: PHI 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>
```

4.4.3.10 Pre-Grazing Interval (PGI)/Pre-Feeding Interval (PFI) Restrictions (+)

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:

ID Numbers	Validation Error Messages
4.4.3.10.1	There is zero to many "Pre-Grazing/Pre-Feeding Interval Restrictions" requirements.
4.4.3.10.2	If Pre-Grazing/Pre-Feeding Interval Restrictions is provided at the Product or Scenario Level, then it should not also be provided at the Site Level.
4.4.3.10.3	Pre-Grazing/Pre-Feeding Interval Restrictions occurs after application. (<sequenceNumber> value must be “3”.)
4.4.3.10.4	Pre-Grazing/Pre-Feeding Interval Restrictions has a code of 1005026 and a displayName of “PGI Category”.
4.4.3.10.5	Pre-Grazing/Pre-Feeding Interval Restrictions displayName must match the code.
4.4.3.10.6	If there is Pre-Grazing/Pre-Feeding Interval Restrictions listed then there must be a <value> element with code and displayName.
4.4.3.10.7	Pre-Grazing/Pre-Feeding Interval Restrictions <value> code and displayName must come from the list "PGI Category".
4.4.3.10.8	Pre-Grazing/Pre-Feeding Interval Restrictions <value> displayName must match the code.
4.4.3.10.9	There is zero or one animal “Weight” or “Age” per Pre-Grazing/Pre-Feeding Interval Restriction.
4.4.3.10.10	Pre-Grazing/Pre-Feeding Interval Restrictions animal “Weight” value is a number.
4.4.3.10.11	Pre-Grazing/Pre-Feeding Interval Restrictions animal “Age” value is a number.
4.4.3.10.12	There is zero or one Pre-Grazing/Pre-Feeding Interval Restrictions - Time per Pre-Grazing/Pre-Feeding Interval Restriction.
4.4.3.10.13	Pre-Grazing/Pre-Feeding Interval Restrictions - Time value is a number.
4.4.3.10.14	Pre-Grazing/Pre-Feeding Interval Restrictions - Units must be units of time or weight, respectively.

Figure 102: PGI/PFI XML Code Snippet

```
<componentOf>
  <protocol>
   <!-- other elements -->
   <!-- (0..*) PGI -->
   <component>
    <!-- after application -->
    <sequenceNumber value="3"/>
    <!-- wait some period of time -->
    <pauseQuantity xsi:type="PQ" nullFlavor="OTH">
     <translation value="{“Interval Time”}"
                  displayName="{“Unit of Measure Display name”}"
                  code="{“UoM Code”}"
                  codeSystem="2.16.840.1.113883.6.275.1"/>
    </pauseQuantity>
    <!-- conduct observation -->
    <monitoringObservation>
     <code code="1005026"
           codeSystem="2.16.840.1.113883.6.275.1"
           displayName=" PGI Category "/>
     <precondition>
      <observationCriterion>
       <code code="3608438"
             codeSystem="2.16.840.1.113883.6.275.1"
             displayName="Animals weighing less than ___"/>
       <!-- Animal Weight / Age -->
       <value xsi:type="PQ" nullFlavor="OTH">
        <translation value="5"
                     displayName="pound"
                     code="3627071"
                     codeSystem="2.16.840.1.113883.6.275.1"/>
       </value>
      </observationCriterion>
     </precondition>
    </monitoringObservation>
   </component>
  </protocol>
 </componentOf>
```

4.4.3.11 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:

ID Numbers	Validation Error Messages
4.4.3.11.1	There is zero to many "Pre-Slaughter Interval Restrictions" requirements.
4.4.3.11.2	If Pre-Slaughter Interval Restrictions is provided at the Product or Scenario Level, then it should not also be provided at the Product Level.
4.4.3.11.3	Pre-Slaughter Interval Restrictions occur after application. (<sequenceNumber> value must be “3”.)
4.4.3.11.4	Pre-Slaughter Interval Restrictions has a code of 1005027 and a displayName of “PSI Category”.
4.4.3.11.5	Pre-Slaughter Interval Restrictions displayName must match the code.
4.4.3.11.6	If there is Pre-Slaughter Interval Restrictions listed then there must be a <value> element with code and displayName.

4.4.3.11.1	There is zero to many "Pre-Slaughter Interval Restrictions" requirements.
4.4.3.11.7	Pre-Slaughter Interval Restrictions <value> code and displayName must come from the list "PSI Category".
4.4.3.11.8	Pre-Slaughter Interval Restrictions <value> displayName must match the code.
4.4.3.11.9	There is zero or one Pre-Slaughter Interval Restrictions - Time per Pre-Slaughter Interval Restriction.
4.4.3.11.10	Pre-Slaughter Interval Restrictions - Time value is a number.
4.4.3.11.11	Pre-Slaughter Interval Restrictions - Units must be units of time.

Figure 103: PSI 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>
```

4.4.3.12 Buffered Area(s) (+)

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:

ID Numbers	Validation Error Messages
4.4.3.12.1	There is zero to many "Buffered Area(s)" preconditions.
4.4.3.12.2	If Buffered Area(s) is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.12.3	Buffered Area(s) <checkPoint> code is "T".

4.4.3.12.1	There is zero to many "Buffered Area(s)" preconditions.
4.4.3.12.4	Buffered Area(s) has a code of 1004980 and a displayName of “Buffered Area”.
4.4.3.12.5	Buffered Area(s) displayName must match the code.
4.4.3.12.6	If there is Buffered Area(s) listed then there must be a <value> element with code and displayName.
4.4.3.12.7	Buffered Area(s) <value> code and displayName must come from the list "Buffered Area".
4.4.3.12.8	Buffered Area(s) <value> displayName must match the code.
4.4.3.12.9	Buffered Area(s) - Distance value is a number.
4.4.3.12.10	Buffered Area(s) - Units must be "Standard Length" units.

Figure 104: Buffered Areas 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>
```

4.4.3.13 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:

ID Numbers	Validation Error Messages
4.4.3.13.1	There is zero or one "Maximum Release Height" preconditions.
4.4.3.13.2	If Max Release Height is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.13.3	Max Release Height <checkPoint> code is "T".
4.4.3.13.4	Max Release Height - Height value is a number.
4.4.3.13.5	Max Release Height - Units must be "Standard Length" units.

Figure 105: Maximum Release Height 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>
```

4.4.3.14 Max Wind Speed

Identifies the maximum wind speed allowed during application.

Entry type: Value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.3.14.1	There is zero or one "Maximum Wind Speed" preconditions.
4.4.3.14.2	If Max Wind Speed is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.14.3	Max Wind Speed <checkPoint> code is "T".
4.4.3.14.4	Max Wind Speed - Speed value is a number.
4.4.3.14.5	Max Wind Speed - Units must be units of speed.

Figure 106: Maximum Wind Speed 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>
```

4.4.3.15 Application Temperature

Identifies the minimum and/or maximum temperature(s) at which application(s) may be made.

Entry type: Value unit, value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.3.15.1	There is zero or one "Application Temperature" preconditions.
4.4.3.15.2	If Application Temperature is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.15.3	Application Temperature <checkPoint> code is "B".
4.4.3.15.4	Application Temperature - Min Temp value is a number.
4.4.3.15.5	Application Temperature - Max Temp value is a number.
4.4.3.15.6	Application Temperature - Units (Min Temp/Max Temp) must be temperature units.
4.4.3.15.7	Application Temperature - Units must match when both limits are provided.
4.4.3.15.8	"Min Temp" and "Max Temp" do not need to be provided together.

Figure 107: Application Temperature 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>
```

4.4.3.16 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:

ID Numbers	Validation Error Messages
4.4.3.16.1	There is zero to many "ASABE Droplet Size" requirements.
4.4.3.16.2	If ASABE Droplet Size is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.16.3	ASABE Droplet Size is **required** when Application Type = "broadcast", Form as Applied = "liquid formations" and/or Application Equipment = "Aerial"' or "Groundboom".
4.4.3.16.4	ASABE Droplet Size has a code of 1004962 and a displayName of "ASABE Droplet Size".
4.4.3.16.5	ASABE Droplet Size displayName must match the code.
4.4.3.16.6	If there is ASABE Droplet Size listed then there must be a <value> element with code and displayName.
4.4.3.16.7	ASABE Droplet Size <value> code and displayName must come from the list "ASABE Droplet Size".
4.4.3.16.8	ASABE Droplet Size <value> displayName must match the code.

Figure 108: ASABE Droplet Size XML Code Snippet

```
<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>
```

4.4.3.17 Soil Incorporation Depth and Time

Identifies the minimum soil incorporation depth that is required for the application, and the maximum amount of time that must 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:

ID Numbers	Validation Error Messages
4.4.3.17.1	There is zero or one "Soil Incorporation Depth and Time" observations.
4.4.3.17.2	If Soil Incorporation Depth and Time is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.17.3	Soil Incorporation Depth and Time restriction occurs after application. (<sequenceNumber> value must be "3".)
4.4.3.17.4	If soil incorporation occurs at the time of application then “Time” is “0” and “Units” are “minutes”.
4.4.3.17.5	If there is a soil incorporation “Time” then there should also be a soil incorporation “Depth”.
4.4.3.17.6	Soil Incorporation Depth and Time - Units must be units of time and "Standard Length", respectively.

Figure 109: Soil Incorporation Depth and Time 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>
```

4.4.3.18 Restricted Soil Type (+)

Identifies any soil type(s) to which the product should not be applied using the prescribed methods.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.3.18.1	There is zero to many "Restricted Soil Type(s)" preconditions.
4.4.3.18.2	If Restricted Soil Type(s) is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.18.3	Restricted Soil Type(s) <checkPoint> code is "B".
4.4.3.18.4	Restricted Soil Type(s) has a code of 1004961 and a displayName of “Soil Type”.
4.4.3.18.5	Restricted Soil Type(s) displayName must match the code.
4.4.3.18.6	If there is Restricted Soil Type(s) listed then there must be a <value> element with code and displayName.
4.4.3.18.7	Restricted Soil Type(s) <value> code and displayName must come from the list "Soil Type".
4.4.3.18.8	Restricted Soil Type(s) <value> displayName must match the code.

Figure 110: Restricted Soil Type 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>
```

4.4.3.19 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:

ID Numbers	Validation Error Messages
4.4.3.19.1	There is zero or one "Minimum Percent Soil Organic Matter" preconditions.
4.4.3.19.2	If Minimum Percent Soil Organic Matter is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.19.3	Minimum Percent Soil Organic Matter <checkPoint> code is "B".
4.4.3.19.4	Minimum Percent Soil Organic Matter - Value is a number.
4.4.3.19.5	Minimum Percent Soil Organic Matter has a unit code of 3627136 and a displayName of "%".

Figure 111: Minimum Percent Soil Organic Matter 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>
```

4.4.3.20 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:

ID Numbers	Validation Error Messages
4.4.3.20.1	There is zero or one "Minimum Age of Animal To Be Treated" preconditions.
4.4.3.20.2	If Minimum Age of Animal To Be Treated is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.20.3	Minimum Age of Animal To Be Treated <checkPoint> code is "B".
4.4.3.20.4	Minimum Age of Animal To Be Treated - Age value is a number.
4.4.3.20.5	Minimum Age of Animal To Be Treated - Units must be units of time.

Figure 112: Minimum Age of Animal To Be Treated 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>
```

4.4.3.21 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:

ID Numbers	Validation Error Messages
4.4.3.21.1	There is zero or one "Minimum Weight of Animal To Be Treated" preconditions.
4.4.3.21.2	If Minimum Weight of Animal To Be Treated is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.21.3	Minimum Weight of Animal To Be Treated <checkPoint> code is "B".
4.4.3.21.4	Minimum Weight of Animal To Be Treated - Weight value is a number.
4.4.3.21.5	Minimum Weight of Animal To Be Treated - Units must be "Standard Weight/Mass" units.

Figure 113: Minimum Weight of Animal To Be Treated 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>
```

4.4.3.22 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:

ID Numbers	Validation Error Messages
4.4.3.22.1	There is zero to many "Pollinator Protection Statement(s)" requirements.
4.4.3.22.2	If Pollinator Protection Statement(s) is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.22.3	Pollinator Protection Statement(s) has a code of 1005022 and a displayName of "Pollinator Protection Statements".
4.4.3.22.4	Pollinator Protection Statement(s) displayName must match the code.
4.4.3.22.5	If there is Pollinator Protection Statement(s) listed then there must be a <value> element with code and displayName.
4.4.3.22.6	Pollinator Protection Statement(s) <value> code and displayName must come from the list "Pollinator Protection Statements".
4.4.3.22.7	Pollinator Protection Statement(s) <value> displayName must match the code.

Figure 114: Pollinator Protection Statements 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>
```

4.4.3.23 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:

ID Numbers	Validation Error Messages
4.4.3.23.1	There is zero or one "Bulletins Live" requirements.
4.4.3.23.2	If Bulletins Live is provided at the Product or Scenario Level, then it should not also provided at the Site Level.

Figure 115: Bulletins Live 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>
```

4.4.3.24 Applications to Water (+)

Identifies specific label restrictions related to the treatment of a volume of water including flooded field applications and other water bodies. 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:

ID Numbers	Validation Error Messages
4.4.3.24.1	There is zero to many "Water Protection Statement(s)" requirements.
4.4.3.24.2	If Water Protection Statement(s) is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.24.3	Water Protection Statement(s) has a code of 1005023 and a displayName of "Water Protection Statements".
4.4.3.24.4	Water Protection Statement(s) displayName must match the code.
4.4.3.24.5	If there is Water Protection Statement(s) listed then there must be a <value> element with code and displayName.
4.4.3.24.6	Water Protection Statement(s) <value> code and displayName must come from the list "Water Protection Statements".
4.4.3.24.7	Water Protection Statement(s) <value> displayName must match the code.
4.4.3.24.8	Water Protection Statement(s) - Value is a number.
4.4.3.24.9	Water Protection Statement(s) - Units must be provided.

Figure 116: Water Protection Statement XML Code Snippet

```
<!-- (0..*) Applications to Water -->
 <component>
  <!-- after application -->
  <sequenceNumber value="3"/>
  <!-- conduct observation -->
  <monitoringObservation>
   <code code="1005023"
         codeSystem="2.16.840.1.113883.6.275.1"
         displayName="Water Protection Statement"/>
   <precondition>
    <observationCriterion>
     <code code="{Water Protection Statement Code}"
           codeSystem="2.16.840.1.113883.6.275.1"
           displayName="{Water Protection Statement}"/>
     <value xsi:type="PQ" nullFlavor="OTH">
      <translation code="{Unit Code}"
                   codeSystem="2.16.840.1.113883.6.275.1"
                   displayName="{Unit DisplayName}"
                   value="{Some Value}"/>
     </value>
    </observationCriterion>
   </precondition>
  </monitoringObservation>
 </component>
```

4.4.3.25 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 manufacturing appear on the label then Secondary Manufacturing should be selected.

Entry type: Presence/absence selection.

Validation Procedures:

ID Numbers	Validation Error Messages
4.4.3.25.1	There is zero or one "Secondary Manufacturing" requirements.
4.4.3.25.2	If Secondary Manufacturing is provided at the Product or Scenario Level, then it should not also provided at the Site Level.

Figure 117: Secondary Manufacturing 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>
```

4.4.3.26 Restricted Use Site Location (+)

Identifies if applications are not permitted in specific Use Site Locations. Locations entered as restricted at the Site Level 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:

ID Numbers	Validation Error Messages
4.4.3.26.1	There is zero to many "Restricted Use Site Location(s)" preconditions.
4.4.3.26.2	If Restricted Use Site Location(s) is provided at the Product or Scenario Level, then it should not also be provided at the Site Level.
4.4.3.26.3	Restricted Use Site Location(s) <checkPoint> code is "B".
4.4.3.26.4	Restricted Use Site Location(s) has a code of 1004663 and a displayName of "Use Site Location".
4.4.3.26.5	Restricted Use Site Location(s) displayName must match the code.
4.4.3.26.6	If there is Restricted Use Site Location(s) listed then there must be a <value> element with code and displayName.
4.4.3.26.7	Restricted Use Site Location(s) <value> code and displayName must come from the list "Use Site Location".
4.4.3.26.8	Restricted Use Site Location(s) <value> displayName must match the code.

Figure 118: Use Site Location 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>
```

4.4.3.27 Restricted Application Target (+)

Identifies if applications are not permitted to specific targets. Targets entered as restricted at the Site Level 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:

ID Numbers	Validation Error Messages
4.4.3.27.1	There is zero to many "Restricted Application Target(s)" preconditions.
4.4.3.27.2	If Restricted Application Target(s) is provided at the Product or Scenario Level, then it should not also be provided at the Site Level.
4.4.3.27.3	Restricted Application Target(s) <checkPoint> code is "B".
4.4.3.27.4	Restricted Application Target(s) has a code of 1004682 and a displayName of "Application Target".
4.4.3.27.5	Restricted Application Target(s) displayName must match the code.
4.4.3.27.6	If there is Restricted Application Target(s) listed then there must be a <value> element with code and displayName.
4.4.3.27.7	Restricted Application Target(s) <value> code and displayName must come from the list "Application Target".
4.4.3.27.8	Restricted Application Target(s) <value> displayName must match the code.

Figure 119: Restricted Application Target 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>
```

4.4.3.28 Restricted Application Type (+)

Identifies if applications are not permitted using specific application types. Application types entered as restricted at the Site Level 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:

ID Numbers	Validation Error Messages
4.4.3.28.1	There is zero to many "Restricted Application Type(s)" preconditions.
4.4.3.28.2	If Restricted Application Type(s) is provided at the Product or Scenario Level, then it should not also be provided at the Site Level.
4.4.3.28.3	Restricted Application Type(s) <checkPoint> code is "B".
4.4.3.28.4	Restricted Application Type(s) has a code of 1004920 and a displayName of "Application Type".
4.4.3.28.5	Restricted Application Type(s) displayName must match the code.
4.4.3.28.6	If there is Restricted Application Type(s) listed then there must be a <value> element with code and displayName.
4.4.3.28.7	Restricted Application Type(s) <value> code and displayName must come from the list "Application Type".
4.4.3.28.8	Restricted Application Type(s) <value> displayName must match the code.

Figure 120: Restriced Application Type 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"
                displayName="{Application Type DisplayName}"/>
            <!-- not the condition -->
            <valueNegationInd value="true"/>
          </observationCriterion>
        </precondition>
```

4.4.3.29 Restricted Application Equipment (+)

Identifies if applications are not permitted using specific equipment. Equipment entered as restricted at the Site Level 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:

ID Numbers	Validation Error Messages
4.4.3.29.1	There is zero to many "Restricted Application Equipment" preconditions.
4.4.3.29.2	If Restricted Application Equipment is provided at the Product or Scenario Level, then it should not also provided at the Site Level.
4.4.3.29.3	"Restricted Application Equipment" <checkPoint> code is "B".
4.4.3.29.4	Restricted Application Equipment has a code of 1004922 and a displayName of "Application Equipment".
4.4.3.29.5	Restricted Application Equipment displayName must match the code.
4.4.3.29.6	If there is Restricted Application Equipment listed then there must be a <value> element with code and displayName.
4.4.3.29.7	Restricted Application Equipment <value> code and displayName must come from the list "Application Equipment".
4.4.3.29.8	Restricted Application Equipment <value> displayName must match the code.

Figure 121: Restriced Application Equipment 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"/>
          </observationCriterion>
        </precondition>
```

4.4.3.30 Restricted Application Timing (+)

Identifies if applications are not permitted during specific timings. Timings entered as restricted at the Site Level 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:

ID Numbers	Validation Error Messages
4.4.3.30.1	There is zero to many "Restricted Application Timing (Use Site Status)", "Restricted Application Timing (Time of Day)", and/or "Restricted Application Timing (Timing of Pest)" preconditions.
4.4.3.30.2	If Restricted Application Timing is provided at the Product or Scenario Level, then it should not also be provided at the Site Level.
4.4.3.30.3	Restricted Application Timing <checkPoint>Code code is "B".
4.4.3.30.4	Restricted Application Timing (Time of Day) has a code of 1004921 and a displayName of “Application Timing (Time of Day)”.
4.4.3.30.5	Restricted Application Timing (Timing of Pest) has a code of 1005020 and a displayName of “Application Timing (Timing of Pest)”.
4.4.3.30.6	Restricted Application Timing (Use Site Status) has a code of 1004960 and a displayName of “Application Timing (Use Site Status)”.
4.4.3.30.7	Restricted Application Timing displayName must match the code.
4.4.3.30.8	If there is Restricted Application Timing listed then there must be a <value> element with code and displayName.
4.4.3.30.9	Restricted Application Timing (Time of Day) <value> code and displayName must come from the list "Application Timing (Time of Day)".
4.4.3.30.10	Restricted Application Timing (Timing of Pest) <value> code and displayName must come from the list "Application Timing (Timing of Pest)".
4.4.3.30.11	Restricted Application Timing (Use Site Status) <value> code and displayName must come from the list "Application Timing (Use Site Status)".
4.4.3.30.12	Restricted Application Timing <value> displayName must match the code.

Figure 122: Restricted Application Timing 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 -->
            <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>
```

4.5 Scenario Level (+)

4.5.0 Section in General

The Scenario Level section is a sub-section of a Site Level and is a header section to contain the child sections below defined. The Scenario Level section can be repeated/cloned to create many scenarios within a Site Level section.

A scenario describes specific instructions for how to use the product. Each scenario is defined using 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 Scenario Level is to capture the maximum overall rate for the application 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 Restrictions" when rates differ based on geography. Before entering information to define a scenario, look across the application instructions for the site to determine if there are unique use parameters. For example, if there are different application rates associated with a pre-plant, soil in-furrow application versus a post emergent foliar application, then a separate scenario is entered for each. Conversely, if the parameters do not change with variations in equipment, timing, application type, or target, then a single scenario can capture all the details. It is important to remember, however, that all combinations of selections must be permitted.

Information entered in the Scenario Level subsections applies to all combinations of the Scenario Attributes listed.

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.0.0.1	There is at least one "Scenario Level" section per Site Level section.
4.5.0.0.2	Scenario Level section <title> and displayName must match.
4.5.0.0.3	Scenario Level section link is optional.
4.5.0.0.4	If Scenario Level section link is provided then the section link is a unique string within the Use Index document.
4.5.0.0.5	Scenario Level <section ID> is a unique UUID within the Use Index document.

Figure 123: Scenario Level Section 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>
```

4.5.1 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:

ID Numbers	Validation Error Messages
4.5.1.0.1	There is one "Scenario Rate" sub-section per Scenario Level section.
4.5.1.0.2	Scenario Rate section <title> and displayName must match.
4.5.1.0.3	Scenario Rate section link is optional.
4.5.1.0.4	If Scenario Rate section link is provided then the section link is a unique string within the Use Index document.
4.5.1.0.5	Scenario Rate <section ID> is a unique UUID within the Use Index document.
4.5.1.0.6	Scenario Rate must be less than the Use Site Yearly/Crop Cycle Rate when Unit of Measure codes are the same.

Figure 124: Scenario Rate 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>
```

4.5.1.1 Single Application Minimum Rate

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, the single application rate is the quantity of product that can be applied per day (24 hours) to the respective 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 a product can be applied with a particular combination of Scenario Attributes.

Typically, conventional pesticide use rates are expressed in terms of amount of product per area treated. However, some rates will require non-area based units; e.g., “per 100 pounds of seed”, “per animal”, “per volume”, “per second”, etc.

Similarly, antimicrobial use rates will typically be expressed in terms of amount of product per amount of treated material. However, some rates may be expressed as concentration; e.g., “parts per million”, “parts per billion”, “%” based on total product weight”, etc. In these cases, the denominator of the rate should be entered as per “1” “target concentration no area needed”.

Additionally, rates may be expressed as a finished spray (maximum amount of product per minimum volume of diluent, with the maximum total solution applied per area) by using both the “Single Application Rate” and “Minimum Diluent/Carrier or Maximum Finish Spray Volume per Area” data entry points. To do this, the “Single Application Rate” is entered as a spray solution concentration, where the denominator of the rate represents the minimum quantity of diluent that the entered quantity of product may be mixed with. The “Minimum Diluent/Carrier or Maximum Finish Spray Volume per Area” data element below is then used to record the maximum amount of spray solution that can be applied per area. If the denominator of the rate entered in the “Single Application Rate” data field is a volume, and the Application Target is not water or treated material, then it will be assumed that the value is in terms of the finish spray.

Entry type: Value unit, value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.1.1.1	There is zero or one "Single Application Minimum Rate" per Scenario Level section.
4.5.1.1.2	Single Application Minimum Rate xsi:type is "RTO_PQ_PQ".
4.5.1.1.3	Single Application Minimum Rate numerator value is a number.
4.5.1.1.4	Single Application Minimum Rate denominator value is a number.
4.5.1.1.5	Single Application Minimum Rate numerator units must match Single Application Maximum Rate numerator units when both are provided.
4.5.1.1.6	Single Application Minimum Rate denominator units must match Single Application Maximum Rate denominator units when both are provided.
4.5.1.1.7	Single Application Minimum Rate numerator units must be one of the following: "Standard Weight/Mass"; "Standard Volume/Capacity"; "Miscellaneous Application Unit"; "Concentration"; "Non-Standard Volume/Capacity".
4.5.1.1.8	"Single Application Minimum Rate" denominator units must be one of the following: "Standard Area"; " Standard Length"; "Standard Weight/Mass"; "Standard Volume/Capacity"; "Time"; "Non-Standard Volume/Capacity"; "Non-standard - Target (with acreage rate limit)"; "Non-Standard Weight/Mass".
4.5.1.1.9	If there is a Single Application Minimum Rate numerator value then there must also be a denominator value.

4.5.1.2 Single Application Maximum Rate

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, the single application rate is the quantity of product that can be applied per day (24 hours) to the respective 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 a product can be applied with a particular combination of Scenario Attributes.

Typically, conventional pesticide use rates will be expressed in terms of amount of product per area treated. However, some rates will require non-area based units; e.g., “per 100 pounds of seed”, “per animal”, “per volume”, “per second”, etc.

Similarly, antimicrobial use rates will typically be expressed in terms of amount of product per amount of treated material. Some rates, however, may be expressed as concentration; e.g., “parts per million”, “parts per billion”, “%” based on total product weight”, etc. In these cases, the denominator of the rate should be entered as per “1” “target concentration no area needed”.

Additionally, rates may be expressed as a finished spray (maximum amount of product per minimum volume of diluent, with the maximum total solution applied per area) by using both the “Single Application Rate” and “Minimum Diluent/Carrier or Maximum Finish Spray Volume per Area” data entry points. To do this, the “Single Application Rate” is entered as a spray solution concentration, where the denominator of the rate represents the minimum quantity

of diluent that the entered quantity of product may be mixed with. The “Minimum Diluent/Carrier or Maximum Finish Spray Volume per Area” data element below is then used to record the maximum amount of spray solution that can be applied per area. If the denominator of the rate entered in the “Single Application Rate” data field is a volume, and the Application Target is not water or treated material, then it will be assumed that the value is in terms of the finish spray.

Entry type: Value unit, value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.1.2.1	"Single Application Maximum Rate" is required per each Scenario Level section.
4.5.1.2.2	Single Application Maximum Rate numerator value is a number.
4.5.1.2.3	Single Application Maximum Rate denominator value is a number.
4.5.1.2.4	Single Application Maximum Rate numerator units must be one of the following: "Standard Weight/Mass"; "Standard Volume/Capacity"; "Miscellaneous Application Unit"; " Concentration"; "Non-Standard Volume/Capacity".
4.5.1.2.5	Single Application Maximum Rate denominator units must be one of the following: "Standard Area"; "Standard Length"; "Standard Weight/Mass"; "Standard Volume/Capacity"; "Time"; "Non-Standard Volume/Capacity"; "Non-standard - Target (with acreage rate limit)"; "Non-Standard Weight/Mass"; "Miscellaneous – Target".
4.5.1.2.6	If there is a Single Application Maximum Rate numerator value then there must also be a denominator value.

Figure 125: Single Application Rate Range 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>
       <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>
```

4.5.1.3 Acre Rate for Non-Standard Target Measures

Identifies the mass of product that can be applied per day (24 hours) 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 Rate (see units terminology in the **SmartLabel Vocabulary Guide Version 3.xlsx** 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, value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.1.3.1	There is zero or one "Acre Rate for Non-Standard Target Measures" characteristics per Scenario Level section.
4.5.1.3.2	Acre Rate for Non-Standard Target Measures xsi:type is "RTO_PQ_PQ".
4.5.1.3.3	Acre Rate for Non-Standard Target Measures is required if Single Application Maximum Rate units are "Non-standard - Target (with acreage rate limit)".
4.5.1.3.4	Acre Rate for Non-Standard Target Measures numerator value is a number.
4.5.1.3.5	Acre Rate for Non-Standard Target Measures denominator value is a number.
4.5.1.3.6	Acre Rate for Non-Standard Target Measures numerator units must be one of the following: "Standard Weight/Mass"; "Standard Volume/Capacity"; "Miscellaneous Application Unit"; "Concentration"; "Non-Standard Volume/Capacity".
4.5.1.3.7	Acre Rate for Non-Standard Target Measures denominator units must be one of the following: "Standard Area"; "Standard Length"; "Standard Weight/Mass"; "Standard Volume/Capacity"; "Time"; "Non-Standard Volume/Capacity"; "Non-standard - Target (with acreage rate limit)"; "Non-Standard Weight/Mass"; "Miscellaneous – Target".
4.5.1.3.8	If there is an Acre Rate for Non-Standard Target Measures numerator value then there must also be a denominator value.

Figure 126: Acre Rate 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>
```

4.5.1.4 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 Form as Applied in the Scenario Attributes subsection is a liquid and nothing is entered in this field it signifies that the product does not need to be diluted prior to application; i.e., the product is in a ready-to-use form.

Entry type: Value unit, value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.1.4.1	There is zero or one "Minimum Diluent/Carrier or Maximum Finish Spray Volume per Area" per Scenario Level section.
4.5.1.4.2	Minimum Diluent/Carrier or Maximum Finish Spray Volume per Area xsi:type is "RTO_PQ_PQ".
4.5.1.4.3	Minimum Diluent/Carrier or Maximum Finish Spray Volume per Area is required when "Form as Applied" is a liquid.
4.5.1.4.4	Minimum Diluent/Carrier or Maximum Finish Spray Volume per Area numerator value is a number.
4.5.1.4.5	Minimum Diluent/Carrier or Maximum Finish Spray Volume per Area denominator value is a number.
4.5.1.4.6	Minimum Diluent/Carrier or Maximum Finish Spray Volume per Area numerator units must be one of the following: "Standard/Volume Capacity"; " Standard Weight/Mass".
4.5.1.4.7	Minimum Diluent/Carrier or Maximum Finish Spray Volume per Area denominator 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".

Figure 127: Minimum Diluent Volume 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>
```

4.5.1.5 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:

ID Numbers	Validation Error Messages
4.5.1.5.1	There is zero or one "Residence/Contact Time" per Scenario Level section.
4.5.1.5.2	Residence/Contact Time xsi:type is "PQ".
4.5.1.5.3	Residence/Contact Time is required for products where contact time is required for efficacy.
4.5.1.5.4	Residence/Contact Time - Min Time value is a number.
4.5.1.5.5	Residence /Contact Time - Units must be time units.

Figure 128: Residence/Contact Time 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>
```

4.5.1.6 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 respective Use Site using all Scenarios combined, as indicated in Maximum Number of Applications per Site per Time.

Enter information here and for “Maximum Application Rate per Scenario per Time” as either per year or per crop cycle; not both.

If “Maximum Number of Applications per Scenario per Time” or “Maximum Application Rate per Scenario per Time” are expressed in terms of “per Crop Cycle”, then “Maximum Number of Crop Cycles per Year” must also be provided.

Entry type: Value per “*Application Rate Measurement Period”* picklist selection.

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.1.6.1	At least one, "Maximum Number of Applications per Scenario per Time" or "Maximum Application Rate per Scenario per Time", must be provided.
4.5.1.6.2	Maximum Number of Applications per Scenario per Time xsi: type is "PQ".
4.5.1.6.3	Maximum Number of Applications per Scenario per Time - Number value is a number.
4.5.1.6.4	Maximum Number of Applications per Scenario per Time - Per Time units must be "Year" or "Crop Cycle".

4.5.1.6.1	At least one, "Maximum Number of Applications per Scenario per Time" or "Maximum Application Rate per Scenario per Time", must be provided.
4.5.1.6.5	Maximum Number of Applications per Scenario per Time <methodCode> is from the list "Application Rate Measurement Period".
4.5.1.6.1	At least one, "Maximum Number of Applications per Scenario per Time" or "Maximum Application Rate per Scenario per Time", must be provided.
4.5.1.6.2	Maximum Number of Applications per Scenario per Time xsi: type is "PQ".

Figure 129: Maximim Number of Applications 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>
```

4.5.1.7 Minimum Application Rate per Scenario per Time

The maximum yearly/crop cycle application rate is entered in as a numerical range with a given unit per 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).

Typically, conventional pesticide use rates will be expressed in terms of amount of product per area treated. However, some rates will require non-area based units; e.g., “per 100 pounds of seed”, “per animal”, “per volume”, “per second”, etc.

Similarly, antimicrobial use rates will typically be expressed in terms of amount of product per amount of treated material. Some rates, however, may be expressed as concentration; e.g., “parts per million”, “parts per billion”, “%” based on total product weight”, etc. In these cases, the denominator of the rate should be entered as per “1” “target concentration no area needed”.

Enter information here and for “Maximum Number of Applications per Scenario per Time” as either per year or per crop cycle; not both.

If “Maximum Number of Applications per Scenario per Time” or “Maximum Application Rate per Scenario per Time” are expressed in terms of “per Crop Cycle”, then “Maximum Number of Crop Cycles per Year" must also be provided.

Entry type: Value unit per value unit “*Application Rate Measurement Period”* picklist selection.

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.1.7.1	There is zero or one "Minimum Application Rate per Scenario per Time" per Scenario Level section.
4.5.1.7.2	Minimum Application Rate per Scenario per Time xsi: type is "RTO_PQ_PQ" and nullFlavor is "OTH".
4.5.1.7.3	Minimum Application Rate per Scenario per Time numerator units must match Maximum Application Rate per Scenario per Time numerator units when both are provided.
4.5.1.7.4	Minimum Application Rate per Scenario per Time denominator units must match Maximum Application Rate per Scenario per Time denominator units when both are provided.
4.5.1.7.5	Minimum Application Rate per Scenario per Time numerator value is a number.
4.5.1.7.6	Minimum Application Rate per Scenario per Time denominator value is a number.
4.5.1.7.7	Minimum Application Rate per Scenario per Time numerator units must be one of the following: "Standard Weight/Mass"; "Standard Volume/Capacity"; "Miscellaneous Application Unit"; "Concentration"; "Non-Standard Volume/Capacity".
4.5.1.7.8	Minimum Application Rate per Scenario per Time denominator units must be one of the following: "Standard Area"; "Standard Length"; "Standard Weight/Mass"; "Standard Volume/Capacity"; "Time"; "Non-Standard Volume/Capacity"; "Non-standard - Target (with acreage rate limit)"; "Non-Standard Weight/Mass"; "Miscellaneous – Target".
4.5.1.7.9	Minimum Application Rate per Scenario per Time <methodCode> is from the list "Application Rate Measurement Period".
4.5.1.7.10	If there is a Minimum Application Rate per Scenario per Time numerator value then there must also be a denominator value.

4.5.1.8 Maximum Application Rate per Scenario per Time

The maximum yearly/crop cycle application rate is entered in as a numerical range with a given unit per 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).

Typically, conventional pesticide use rates will be expressed in terms of amount of product per area treated. However, some rates will require non-area based units; e.g., “per 100 pounds of seed”, “per animal”, “per volume”, “per second”, etc.

Similarly, antimicrobial use rates will typically be expressed in terms of amount of product per amount of treated material. However, some rates, may be expressed as concentration; e.g., “parts per million”, “parts per billion”, “%” based on total product weight”, etc. In these cases, the denominator of the rate should be entered as per “1” “target concentration no area needed”.

Enter information here and for “Maximum Number of Applications per Scenario per Time” as either per year or per crop cycle; not both.

If “Maximum Number of Applications per Scenario per Time” or “Maximum Application Rate per Scenario per Time” are expressed in terms of “per Crop Cycle”, then “Maximum Number of Crop Cycles per Year" must also be provided.

Entry type: Value unit per value unit “*Application Rate Measurement Period”* picklist selection.

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.1.8.1	Maximum Application Rate per Scenario per Time xsi: type is "RTO_PQ_PQ" and nullFlavor is "OTH".
4.5.1.8.2	Maximum Application Rate per Scenario per Time numerator value is a number.
4.5.1.8.3	Maximum Application Rate per Scenario per Time denominator value is a number.
4.5.1.8.4	Maximum Application Rate per Scenario per Time numerator units must be one of the following: "Standard Weight/Mass"; "Standard Volume/Capacity"; "Miscellaneous Application Unit"; "Concentration"; "Non-Standard Volume/Capacity".
4.5.1.8.5	Maximum Application Rate per Scenario per Time denominator units must be one of the following: "Standard Area"; "Standard Length"; "Standard Weight/Mass"; "Standard Volume/Capacity"; "Time"; "Non-Standard Volume/Capacity"; "Non-standard - Target (with acreage rate limit)"; "Non-Standard Weight/Mass"; "Miscellaneous – Target".
4.5.1.8.6	Maximum Application Rate per Scenario per Time <methodCode> is from the list "Application Rate Measurement Period".
4.5.1.8.7	If there is a Maximum Application Rate per Scenario per Time numerator value then there must also be a denominator value.

Figure 130: Maximum Application Rate Range XML Code Snippet

```
<title>Scenario Rate</title>
<subject2>
  <substanceAdministration>
          <!-- other elements -->
    <componentOf>
      <protocol>
        <component>
          <substanceAdministration>
                  <!-- other elements -->
            <!-- Minimum Application Rate 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 per Scenario per time -->
            <subjectOf>
              <characteristic>
                <code code="1005321"
                  codeSystem="2.16.840.1.113883.6.275.1"
```

Figure 131: Maximum Application Rate Range XML Code Snippet (Continued)

```
                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>
```

4.5.1.9 Maximum Number of Crop Cycles per Year

Identifies the number of crop cycles per annual (12 month) period. This indicator is necessary when rates at the Site Level or Scenario Level are based on a crop cycle rather than per year.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.1.9.1	There is zero or one "Maximum Number of Crop Cycles per Year" per Scenario Level section.
4.5.1.9.2	Maximum Number of Crop Cycles per Year is required if rates are given per "crop cycle" on the label for this site.
4.5.1.9.3	Maximum Number of Crop Cycles per Year - Number value is a number.
4.5.1.9.4	Maximum Number of Crop Cycles per Year has a unit code of 3627146 and a displayName of "year".

Figure 132: Maximum Number of Crop Cycles per 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>
```

4.5.2 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.

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.2.0.1	There is one "Scenario Attributes" sub-section per Scenario Level section.
4.5.2.0.2	Scenario Attributes section <title> and displayName must match.
4.5.2.0.3	Scenario Attributes section link is optional.
4.5.2.0.4	If Scenario Attributes section link is provided then the section link is a unique string within the Use Index document.
4.5.2.0.5	Scenario Attributes <section ID> is a unique UUID within the Use Index document.

Figure 133: Scenario Attributes XML Code Snippet

```
<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>
```

4.5.2.1 Form as Applied

Identifies the product form at the time of application. This value may be the same or different from Form as Packaged, depending on whether the product is mixed before application or undergoes a physical state change during application.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.2.1.1	"Form as Applied" is required per each Scenario Level section.
4.5.2.1.2	There is one Form as Applied <formCode>.
4.5.2.1.3	Form as Applied <formCode> is from the list "Physical Form".
4.5.2.1.4	Form as Applied displayName must match the code.

Figure 134: Form As Applied XML Code Snippet

```
<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>
```

4.5.2.2 Application Target (+)

Identifies what is physically treated during application/where application of the product is directed; e.g., foliage/plant, soil, human/animal, etc.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.2.2.1	There is at least one to many "Application Target(s)" per Scenario Level section.
4.5.2.2.2	Application Target(s) <targetSiteCode> is from the list "Application Target".
4.5.2.2.3	Application Target(s) displayName must match the code.
4.5.2.2.4	Application Target(s) cannot be restricted at the Product or Site Level.

Figure 135: Application Target 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}"/>
```

4.5.2.3 Application Type (+)

Identifies the specific method(s) for product application; e.g., broadcast, dip treatment, material incorporation, etc.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.2.3.1	There is at least one to many "Application Type(s)" per Scenario Level section.
4.5.2.3.2	Application Type(s) <methodCode> is from the list "Application Type".
4.5.2.3.3	Application Type(s) displayName must match the code.
4.5.2.3.4	Application Type(s) cannot be restricted at the Product or Site Level.

Figure 136: Application Type 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}"/>
```

4.5.2.4 Application Equipment (+)

Identifies the type(s) of equipment used during product application; e.g., helicopter, trap/bait station, total-release fogger, etc.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.2.4.1	There is at least one to many "Application Equipment" characteristics per Scenario Level section.
4.5.2.4.2	Application Equipment xsi: type is "SXCM_CD", meaning a set of codes.
4.5.2.4.3	Application Equipment code 1004922 is from the list "Application Equipment".
4.5.2.4.4	Application Equipment displayName must match the code.
4.5.2.4.5	Application Equipment operator attribute is "I", meaning inclusive.
4.5.2.4.6	Application Equipment cannot be restricted at the Product or Site Level.

Figure 137: Application Equipment XML Code Snippet

```
<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>
```

4.5.2.5 Application Timing (Site Status) (+)

Identifies when pesticide application occurs in relation to the use site; e.g., "At transplant", "During bloom", "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 (Timing of Pest).

Entry type: *"Application Timing (Site Status)"* picklist selection.

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.2.5.1	There is at least one to many "Application Timing (Site Status)" characteristics per Scenario Level section.
4.5.2.5.2	Application Timing (Site Status) xsi: type is "SXCM_CD", meaning a set of codes.
4.5.2.5.3	Application Timing (Site Status) code 1005020 is from the list "Application Timing (Site Status)".
4.5.2.5.4	Application Timing (Site Status) displayName must match the code.
4.5.2.5.5	Application Timing (Site Status) operator attribute is "I", meaning inclusive.
4.5.2.5.6	Application Timing (Site Status) cannot be restricted at the Product or Site Level.

Figure 138: Application Timing (Site Status) 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>
```

4.5.2.6 Application Timing (Time of Day) (+)

Identifies when pesticide application occurs in relation to the time of day; e.g., "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:

ID Numbers	Validation Error Messages
4.5.2.6.1	There is zero to many "Application Timing (Time of Day)" characteristics per Scenario Level section.
4.5.2.6.2	Application Timing (Time of Day) xsi: type is "SXCM_CD", meaning a set of codes.
4.5.2.6.3	Application Timing (Time of Day) code 1004960 is from the list "Application Timing (Time of Day)".
4.5.2.6.4	Application Timing (Time of Day) displayName must match the code.
4.5.2.6.5	Application Timing (Time of Day) operator attribute is "I", meaning inclusive.
4.5.2.6.6	Application Timing (Time of Day) cannot be restricted at the Product or Site Level.

Figure 139: Application Timing (Time of Day) 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>
```

4.5.2.7 Application Timing (Timing of Pest) (+)

Identifies when a pesticide product should be applied in relation to the targeted pest; e.g., “After weed emergence”, “When pest occurs”, “When damage from pest is observed”, etc. This is required if “All crop/site stages possible (e.g., timing determined solely by pest pressure)” is entered for Application Timing (Site Status). 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:

ID Numbers	Validation Error Messages
4.5.2.7.1	There is zero to many "Application Timing (Timing of Pest)" characteristics per Scenario Level section.
4.5.2.7.2	Application Timing (Timing of Pest) xsi: type is "SXCM_CD", meaning a set of codes.
4.5.2.7.3	Application Timing (Timing of Pest) is required when "All crop stages possible (e.g., timing determined solely by pest pressure)" is selected for Application Timing (Site Status).
4.5.2.7.4	Application Timing (Timing of Pest) code 1004921 is from the list "Application Timing (Timing of Pest)".
4.5.2.7.5	Application Timing (Timing of Pest) displayName must match the code.
4.5.2.7.6	Application Timing (Timing of Pest) operator attribute is "I", meaning inclusive.
4.5.2.7.7	Application Timing (Timing of Pest) cannot be restricted at the Product or Site Level.

Figure 140: Application Timing (Timing of Pest) 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)"/>
        <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>
```

4.5.3 Use Scenario Level Restrictions/Limitations

Identifies only Scenario Level Restrictions/Limitations. Restrictions/limitations are entered at this level if they differ between scenarios. Restriction/limitation information 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 data element blank indicates that the respective restriction does not apply at this level.

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.3.0.1	There is one "Use Scenario Level Restrictions/Limitations" sub-section per Scenario Level section.
4.5.3.0.2	Use Scenario Level Restrictions/Limitations section <title> and displayName must match.
4.5.3.0.3	Use Scenario Level Restrictions/Limitations section link is optional.

4.5.3.0.1	There is one "Use Scenario Level Restrictions/Limitations" sub-section per Scenario Level section.
4.5.3.0.4	If Use Scenario Level Restrictions/Limitations section link is provided then the section link is a unique string within the Use Index document.
4.5.3.0.5	Use Scenario Level Restrictions/Limitations <section ID> is a unique UUID within the Use Index document.

Figure 141: Use Scenario Level Restrictions/Limitations 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>
```

4.5.3.1 Geographic Area(s) 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 for a specific scenario are not restricted to any particular geographic area, enter "United States". If application is not allowed in a particular area, enter all areas except the prohibited area.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.3.1.1	There is at least one "Geographic Area" per Scenario. The Scenario is considered to have a Geographic Area if it is provided at the Product, Site, or Scenario Level.
4.5.3.1.2	If Geographic Area is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.1.3	Geographic Area has a code of 1005202 and a displayName of "Geographic Area".
4.5.3.1.4	Geographic Area displayName must match the code.
4.5.3.1.5	If there is Geographic Area listed then there must be a <value> element with code and displayName.
4.5.3.1.6	Geographic Area <value> code and displayName must come from the list "Geographic Area".
4.5.3.1.7	Geographic Area <value> displayName must match the code.

Figure 142: Geographic Area 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>
```

4.5.3.2 Use Site Food Site Relationship

Identifies if applications are intended to come in contact with food or feed, which may indicate the need for a pesticide tolerance or a regulatory risk assessment. This information is required for agricultural crops at either the Product, Site, or Scenario levels for each method to establish whether crops may be used as food/feed or may not be used as food/feed. If the product labeling for non-agricultural sites explicitly prohibits applications that may contact food or feed, then "Non-Food/Non-Feed Stream" should be entered.

See definitions in the **SmartLabel Vocabulary Guide Version 3.xlsx** for further guidance.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.3.2.1	There is one "Use Site Food Relationship" per Scenario. A Scenario is considered to have a Use Site Food Relationship if it is provided at the Product, Site, or Scenario Level.
4.5.3.2.2	If Use Site Food Relationship is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.2.3	Use Site Food Relationship has a code of 1005021 and a displayName of “Use Site Food Relationship”.
4.5.3.2.4	Use Site Food Relationship displayName must match the code.
4.5.3.2.5	If there is Use Site Food Relationship listed then there must be a <value> element with code and displayName.
4.5.3.2.6	Use Site Food Relationship <value> code and displayName must come from the list "Use Site Food Relationship".
4.5.3.2.7	Use Site Food Relationship <value> displayName must match the code.

Figure 143: Food Site Relationship 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>
```

4.5.3.3 Maximum Active Ingredient Rate Across Products per Time

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. 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:

ID Numbers	Validation Error Messages
4.5.3.3.1	There is zero or one "Maximum AI Rate Across Products per Time".
4.5.3.3.2	If Maximum AI Rate Across Products per Time is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.3.3	Maximum AI Rate Across Products per Time numerator value is a number.
4.5.3.3.4	Maximum AI Rate Across Products per Time denominator value is a number.

4.5.3.3.1	There is zero or one "Maximum AI Rate Across Products per Time".
4.5.3.3.5	Maximum AI Rate Across Products per Time numerator units must be one of the following: "Standard Weight/Mass", "Standard Volume/Capacity", "Miscellaneous Application Unit", "Concentration", "Non-Standard Volume/Capacity".
4.5.3.3.6	Maximum AI Rate Across Products per Time denominator units must be one of the following: "Standard Area", "Standard Length", "Standard Weight/Mass", "Standard Volume/Capacity", "Time", "Non-Standard Volume/Capacity", "Non-standard - Target (with area rate limit)", "Non-Standard Weight/Mass", "Miscellaneous – Target".
4.5.3.3.7	Maximum AI Rate Across Products per Time <methodCode> is from the list "Application Rate Measurement Period".
4.5.3.3.8	If there is a Maximum AI Rate Across Products per Time numerator value then there must also be a denominator value.

Figure 144: Maximum AI Rate Across Products 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>
```

4.5.3.4 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:

ID Numbers	Validation Error Messages
4.5.3.4.1	There is zero or one "Rotational Crop" requirements.
4.5.3.4.2	If Rotational Crop is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.

Figure 145: Rotational Crop 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>
```

4.5.3.5 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 Restriction, by definition, indicates all other applicators not identified are restricted from using the product.

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.3.5.1	There is zero to many "Applicator Class Restrictions".
4.5.3.5.2	If Applicator Class Restrictions is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.5.3	Applicator Class Restrictions has a code of 1004442 and a displayName of "Applicator Class Restrictions".
4.5.3.5.4	Applicator Class Restrictions displayName must match the code.
4.5.3.5.5	If there is Applicator Class Restrictions listed then there must be a <value> element with code and displayName.
4.5.3.5.6	Applicator Class Restrictions <value> code and displayName must come from the list "Applicator Class Restrictions".
4.5.3.5.7	Applicator Class Restrictions <value> displayName must match the code.

Figure 146: Applicator Class Restrictions 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>
```

4.5.3.6 Personal Protection Equipment (PPE)/Engineering Control (+)

This indicates the PPE and/or engineering controls 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: *"PPE/Engineering Control*" picklist selection.

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.3.6.1	There is zero to many "PPE/Engineering Controls" requirements.
4.5.3.6.2	If PPE/Engineering Controls is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.6.3	Personal Protection Equipment (PPE)/Engineering Controls has a code of 1005024 and a displayName of "PPE/Engineering Controls".
4.5.3.6.4	PPE/Engineering Controls displayName must match the code.
4.5.3.6.5	If there is PPE/Engineering Controls listed then there must be a <value> element with code and displayName.
4.5.3.6.6	PPE/Engineering Controls <value> code and displayName must come from the list "PPE/Engineering Controls".
4.5.3.6.7	PPE/Engineering Controls <value> displayName must match the code.

Figure 147: PPE/Engineering Control 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>
```

4.5.3.7 REI

Identifies the minimum period of time after a pesticide application when entry into the treated area is restricted; i.e., minimum period of time before worker re-entry. It includes WPS and non-WPS re-entry intervals.

Entry type: Value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.3.7.1	There is zero to one "Re-Entry Interval" requirements.
4.5.3.7.2	If Re-Entry Interval is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.7.3	Re-Entry Interval restriction occurs after application. (<sequenceNumber> value must be "3".)
4.5.3.7.4	Re-Entry Interval - Time value is a number.
4.5.3.7.5	Re-Entry Interval - Units must be units of time.

Figure 148: REI 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>
```

4.5.3.8 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:

ID Numbers	Validation Error Messages
4.5.3.8.1	There is zero to one "Minimum Retreatment Interval" requirements.
4.5.3.8.2	If Minimum Retreatment Interval is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.8.3	Minimum Retreatment Interval is required if more than one application is allowed or if the single application rate is not equal to the crop cycle/yearly rate.
4.5.3.8.4	Minimum Retreatment Interval restriction occurs after application. (<sequenceNumber> value must be "3".)
4.5.3.8.5	Minimum Retreatment Interval - Time value is a number.
4.5.3.8.6	Minimum Retreatment Interval - Units must be units of time.

Figure 149: MRI 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>
```

4.5.3.9 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:

ID Numbers	Validation Error Messages
4.5.3.9.1	There is zero to many "Pre-Harvest Interval Restrictions" requirements.
4.5.3.9.2	If Pre-Harvest Interval Restrictions is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.9.3	Pre-Harvest Interval Restrictions occur after application. (<sequenceNumber> value must be "3".)
4.5.3.9.4	Pre-Harvest Interval Restrictions has a code of 1005028 and a displayName of "PHI Category".
4.5.3.9.5	Pre-Harvest Interval Restrictions displayName must match the code.
4.5.3.9.6	If there is Pre-Harvest Interval Restrictions listed then there must be a <value> element with code and displayName.
4.5.3.9.7	Pre-Harvest Interval Restrictions <value> code and displayName must come from the list "PHI Category".
4.5.3.9.8	Pre-Harvest Interval Restrictions <value> displayName must match the code.
4.5.3.9.9	Pre-Harvest Interval Restrictions - Time value is a number.
4.5.3.9.10	Pre-Harvest Interval Restrictions - Units must be units of time.

Figure 150: PHI 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>
```

4.5.3.10 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:

ID Numbers	Validation Error Messages
4.5.3.10.1	There is zero to many "Pre-Grazing/Pre-Feeding Interval Restrictions" requirements.
4.5.3.10.2	If Pre-Grazing/Pre-Feeding Interval Restrictions is provided at the Site Level, then it should not also be provided at the Product Level.
4.5.3.10.3	Pre-Grazing/Pre-Feeding Interval Restrictions occurs after application. (<sequenceNumber> value must be "3".)
4.5.3.10.4	Pre-Grazing/Pre-Feeding Interval Restrictions has a code of 1005026 and a displayName of "PGI Category".
4.5.3.10.5	Pre-Grazing/Pre-Feeding Interval Restrictions displayName must match the code.
4.5.3.10.6	If there is Pre-Grazing/Pre-Feeding Interval Restrictions listed then there must be a <value> element with code and displayName.
4.5.3.10.7	Pre-Grazing/Pre-Feeding Interval Restrictions <value> code and displayName must come from the list "PGI Category".
4.5.3.10.8	Pre-Grazing/Pre-Feeding Interval Restrictions <value> displayName must match the code.

4.5.3.10.1	There is zero to many "Pre-Grazing/Pre-Feeding Interval Restrictions" requirements.
4.5.3.10.9	There is zero or one animal “Weight” or “Age” per Pre-Grazing/Pre-Feeding Interval Restriction.
4.5.3.10.10	Pre-Grazing/Pre-Feeding Interval Restrictions animal “Weight” value is a number.
4.5.3.10.11	Pre-Grazing/Pre-Feeding Interval Restrictions animal “Age” value is a number.
4.5.3.10.12	There is zero or one Pre-Grazing/Pre-Feeding Interval Restrictions - Time per Pre-Grazing/Pre-Feeding Interval Restriction.
4.5.3.10.13	Pre-Grazing/Pre-Feeding Interval Restrictions - Time value is a number.
4.5.3.10.14	Pre-Grazing/Pre-Feeding Interval Restrictions - Units must be units of time or weight, respectively.

Figure 151: PGI/PFI XML Code Snippet

```
<componentOf>
  <protocol>
    <!-- other elements -->
    <!-- (0..*) PGI -->
    <component>
      <!-- after application -->
      <sequenceNumber value="3"/>
      <!-- wait some period of time -->
      <pauseQuantity xsi:type="PQ" nullFlavor="OTH">
        <translation value="{“Interval Time”}"
                     displayName="{“Unit of Measure Display name”}"
                     code="{“UoM Code”}"
                     codeSystem="2.16.840.1.113883.6.275.1"/>
      </pauseQuantity>
      <!-- conduct observation -->
      <monitoringObservation>
        <code code="1005026"
              codeSystem="2.16.840.1.113883.6.275.1"
              displayName=" PGI Category "/>
        <precondition>
          <observationCriterion>
            <code code="3608438"
                  codeSystem="2.16.840.1.113883.6.275.1"
                  displayName="Animals weighing less than ___"/>
            <!-- Animal Weight / Age -->
            <value xsi:type="PQ" nullFlavor="OTH">
              <translation value="5"
                           displayName="pound"
                           code="3627071"
                           codeSystem="2.16.840.1.113883.6.275.1"/>
            </value>
          </observationCriterion>
        </precondition>
      </monitoringObservation>
    </component>
  </protocol>
</componentOf>
```

4.5.3.11 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:

ID Numbers	Validation Error Messages
4.5.3.11.1	There is zero to many "Pre-Slaughter Interval Restrictions" requirements.
4.5.3.11.2	If Pre-Slaughter Interval Restrictions is provided at the Site Level, then it should not also be provided at the Product Level.
4.5.3.11.3	If Pre-Slaughter Interval Restrictions is provided at the Scenario Level, then it should not also be provided at the Product Level.
4.5.3.11.4	Pre-Slaughter Interval Restrictions occur after application. (<sequenceNumber> value must be “3”.)
4.5.3.11.5	Pre-Slaughter Interval Restrictions has a code of 1005027 and a displayName of “PSI Category”.
4.5.3.11.6	Pre-Slaughter Interval Restrictions displayName must match the code.
4.5.3.11.7	If there is Pre-Slaughter Interval Restrictions listed then there must be a <value> element with code and displayName.
4.5.3.11.8	Pre-Slaughter Interval Restrictions <value> code and displayName must come from the list "PSI Category".
4.5.3.11.9	Pre-Slaughter Interval Restrictions <value> displayName must match the code.
4.5.3.11.10	There is zero or one Pre-Slaughter Interval Restrictions - Time per Pre-Slaughter Interval Restriction.
4.5.3.11.11	Pre-Slaughter Interval Restrictions - Time value is a number.
4.5.3.11.12	Pre-Slaughter Interval Restrictions - Units must be units of time.

Figure 152: PSI 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 Time}"
                     code="{Unit Code}"
                     codeSystem="2.16.840.1.113883.6.275.1"
                     displayName="{Unit DisplayName}"/>
           </width>
          </effectiveTime>
        </requirement>
        </component>
```

4.5.3.12 Buffered Area(s) (+)

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:

ID Numbers	Validation Error Messages
4.5.3.12.1	There is zero to many "Buffered Area(s)" preconditions.
4.5.3.12.2	If Buffered Area(s) is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.12.3	Buffered Area(s) <checkPoint> code is "T".
4.5.3.12.4	Buffered Area(s) has a code of 1004980 and a displayName of "Buffered Area".
4.5.3.12.5	Buffered Area(s) displayName must match the code.
4.5.3.12.6	If there is Buffered Area(s) listed then there must be a <value> element with code and displayName.
4.5.3.12.7	Buffered Area(s) <value> code and displayName must come from the list "Buffered Area".
4.5.3.12.8	Buffered Area(s) <value> displayName must match the code.
4.5.3.12.9	Buffered Area(s) - Distance value is a number.
4.5.3.12.10	Buffered Area(s) - Units must be "Standard Length" units.

Figure 153: Buffered Areas 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>
```

4.5.3.13 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:

ID Numbers	Validation Error Messages
4.5.3.13.1	There is zero or one "Maximum Release Height" preconditions.
4.5.3.13.2	If Max Release Height is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.13.3	Max Release Height <checkPoint> code is "T".
4.5.3.13.4	Max Release Height - Height value is a number.
4.5.3.13.5	Max Release Height - Units must be "Standard Length" units.

Figure 154: Maximum Release Height 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>
```

4.5.3.14 Max Wind Speed

Identifies the maximum wind speed allowed during application.

Entry type: Value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.3.14.1	There is zero or one "Maximum Wind Speed" preconditions.
4.5.3.14.2	If Max Wind Speed is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.14.3	Max Wind Speed <checkPoint> code is "T".
4.5.3.14.4	Max Wind Speed - Speed value is a number.
4.5.3.14.5	Max Wind Speed - Units must be units of speed.

Figure 155: Maximum Wind Speed 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>
```

4.5.3.15 Application Temperature

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

Entry type: Value unit, value unit.

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.3.15.1	There is zero or one "Application Temperature" preconditions.
4.5.3.15.2	If Application Temperature is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.15.3	Application Temperature <checkPoint> code is "B".
4.5.3.15.4	Application Temperature - Min Temp value is a number.
4.5.3.15.5	Application Temperature - Max Temp value is a number.
4.5.3.15.6	Application Temperature - Units (Min Temp/Max Temp) must be temperature units.
4.5.3.15.7	Application Temperature - Units must match when both limits are provided.
4.5.3.15.8	"Min Temp" and "Max Temp" do not need to be provided together.

Figure 156: Application Temperature 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>
```

4.5.3.16 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:

ID Numbers	Validation Error Messages
4.5.3.16.1	There is zero to many "ASABE Droplet Size" requirements.
4.5.3.16.2	If ASABE Droplet Size is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.16.3	ASABE Droplet Size is required when Application Type = "broadcast", Form as Applied = "liquid formations" and/or Application Equipment = "Aerial"' or "Groundboom".
4.5.3.16.4	ASABE Droplet Size has a code of 1004962 and a displayName of "ASABE Droplet Size".
4.5.3.16.5	ASABE Droplet Size displayName must match the code.
4.5.3.16.6	If there is ASABE Droplet Size listed then there must be a <value> element with code and displayName.
4.5.3.16.7	ASABE Droplet Size <value> code and displayName must come from the list "ASABE Droplet Size".
4.5.3.16.8	ASABE Droplet Size <value> displayName must match the code.

Figure 157: ASABE Droplet Size XML Code Snippet

```
<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>
```

4.5.3.17 Soil Incorporation Depth and Time

Identifies the minimum soil incorporation depth that is required for the application, and the maximum amount of time that must 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:

ID Numbers	Validation Error Messages
4.5.3.17.1	There is zero or one "Soil Incorporation Depth and Time" observations.
4.5.3.17.2	If Soil Incorporation Depth and Time is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.17.3	Soil Incorporation Depth and Time restriction occurs after application. (<sequenceNumber> value must be "3".)
4.5.3.17.4	If soil incorporation occurs at the time of application then “Time” is “0” and “Units” are “minutes”.
4.5.3.17.5	If there is a soil incorporation “Time” then there should also be a soil incorporation “Depth”.
4.5.3.17.6	Soil Incorporation Depth and Time - Units must be units of time and "Standard Length", respectively.

Figure 158: Soil Incorporation Depth and Time 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>
```

4.5.3.18 Restricted Soil Type(s) (+)

Identifies any soil type(s) to which the product should not be applied using the prescribed method(s).

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

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.3.18.1	There is zero to many "Restricted Soil Type(s)" preconditions.
4.5.3.18.2	If Restricted Soil Type(s) is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.18.3	Restricted Soil Type(s) <checkPoint> code is "B".
4.5.3.18.4	Restricted Soil Type(s) has a code of 1004961 and a displayName of “Soil Type”.
4.5.3.18.5	Restricted Soil Type(s) displayName must match the code.
4.5.3.18.6	If there is Restricted Soil Type(s) listed then there must be a <value> element with code and displayName.
4.5.3.18.7	Restricted Soil Type(s) <value> code and displayName must come from the list "Soil Type".
4.5.3.18.8	Restricted Soil Type(s) <value> displayName must match the code.

Figure 159: Restricted Soil Type 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>
```

4.5.3.19 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:

ID Numbers	Validation Error Messages
4.5.3.19.1	There is zero or one "Minimum Percent Soil Organic Matter" preconditions.
4.5.3.19.2	If Minimum Percent Soil Organic Matter is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.19.3	Minimum Percent Soil Organic Matter <checkPoint> code is "B".
4.5.3.19.4	Minimum Percent Soil Organic Matter - Value is a number.
4.5.3.19.5	Minimum Percent Soil Organic Matter has a unit code of 3627136 and a displayName of "%".

Figure 160: Minimum Percent Soil Organic Matter 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>
```

4.5.3.20 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:

ID Numbers	Validation Error Messages
4.5.3.20.1	There is zero or one "Minimum Age of Animal To Be Treated" preconditions.
4.5.3.20.2	If Minimum Age of Animal To Be Treated is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.20.3	Minimum Age of Animal To Be Treated <checkPoint> code is "B".
4.5.3.20.4	Minimum Age of Animal To Be Treated - Age value is a number.
4.5.3.20.5	Minimum Age of Animal To Be Treated - Units must be units of time.

Figure 161: Minimum Age of Animal To Be Treated 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>
```

4.5.3.21 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:

ID Numbers	Validation Error Messages
4.5.3.21.1	There is zero or one "Minimum Weight of Animal To Be Treated" preconditions.
4.5.3.21.2	If Minimum Weight of Animal To Be Treated is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.21.3	Minimum Weight of Animal To Be Treated <checkPoint> code is "B".
4.5.3.21.4	Minimum Weight of Animal To Be Treated - Weight value is a number.
4.5.3.21.5	Minimum Weight of Animal To Be Treated - Units must be "Standard Weight/Mass" units.

Figure 162: Minimum Weight of Animal To Be Treated 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>
```

4.5.3.22 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:

ID Numbers	Validation Error Messages
4.5.3.22.1	There is zero to many "Pollinator Protection Statement(s)" requirements.
4.5.3.22.2	If Pollinator Protection Statement(s) is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.22.3	Pollinator Protection Statement(s) has a code of 1005022 and a displayName of "Pollinator Protection Statements".
4.5.3.22.4	Pollinator Protection Statement(s) displayName must match the code.
4.5.3.22.5	If there is Pollinator Protection Statement(s) listed then there must be a <value> element with code and displayName.
4.5.3.22.6	Pollinator Protection Statement(s) <value> code and displayName must come from the list "Pollinator Protection Statements".
4.5.3.22.7	Pollinator Protection Statement(s) <value> displayName must match the code.

Figure 163: Pollinator Protection Statements 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>
```

4.5.3.23 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:

ID Numbers	Validation Error Messages
4.5.3.23.1	There is zero or one "Bulletins Live" requirements.
4.5.3.23.2	If Bulletins Live is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.

Figure 164: Bulletins Live 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>
```

4.5.3.24 Applications to Water (+)

Identifies specific label restrictions related to the treatment of a volume of water including flooded field applications and other water bodies. 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:

ID Numbers	Validation Error Messages
4.5.3.24.1	There is zero to many "Water Protection Statement(s)" requirements.
4.5.3.24.2	If Water Protection Statement(s) is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.
4.5.3.24.3	Water Protection Statement(s) has a code of 1005023 and a displayName of "Water Protection Statements".
4.5.3.24.4	Water Protection Statement(s) displayName must match the code.
4.5.3.24.5	If there is Water Protection Statement(s) listed then there must be a <value> element with code and displayName.
4.5.3.24.6	Water Protection Statement(s) <value> code and displayName must come from the list "Water Protection Statements".
4.5.3.24.7	Water Protection Statement(s) <value> displayName must match the code.
4.5.3.24.8	Water Protection Statement(s) - Value is a number.
4.5.3.24.9	Water Protection Statement(s) - Units must be provided.

Figure 165: Water Protection Statement XML Code Snippet

```
<!-- (0..*) Applications to Water -->
 <component>
  <!-- after application -->
  <sequenceNumber value="3"/>
  <!-- conduct observation -->
  <monitoringObservation>
   <code code="1005023"
         codeSystem="2.16.840.1.113883.6.275.1"
         displayName="Water Protection Statement"/>
   <precondition>
    <observationCriterion>
     <code code="{Water Protection Statement Code}"
           codeSystem="2.16.840.1.113883.6.275.1"
           displayName="{Water Protection Statement}"/>
     <value xsi:type="PQ" nullFlavor="OTH">
      <translation code="{Unit Code}"
                   codeSystem="2.16.840.1.113883.6.275.1"
                   displayName="{Unit DisplayName}"
                   value="{Some Value}"/>
     </value>
    </observationCriterion>
   </precondition>
  </monitoringObservation>
 </component>
```

4.5.3.25 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 manufacturing appear on the label then Secondary Manufacturing should be selected.

Entry type: Presence/absence selection.

Validation Procedures:

ID Numbers	Validation Error Messages
4.5.3.25.1	There is zero or one "Secondary Manufacturing" requirements.
4.5.3.25.2	If Secondary Manufacturing is provided at the Product or Site Level, then it should not also be provided at the Scenario Level.

Figure 166: Secondary Manufacturing 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>
```