Agile Product Lifecycle Management for Process

Computer Aided Compliance Screening User Guide

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June 2012

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About This Manual

Agile Product Lifecycle Management for Process Documentation

The Agile Product Lifecycle Management (PLM) for Process documentation set includes Adobe® Acrobat™ PDF files. The Oracle Technology Network (OTN) Web site: http://www.oracle.com/technetwork/documentation/agile-085940.html contains the latest versions of the Agile PLM for Process PDF files. You can view or download these manuals from the Web site, or you can ask your Agile administrator if there is an Agile PLM for Process Documentation folder available on your network from which you can access the Agile PLM for Process documentation (PDF) files.

Note To read the PDF files, you must use the free Adobe Reader™ version 7.0 or later. This program can be downloaded from the Adobe Web site: http://www.adobe.com/.

If you need additional assistance or information, please go to http://metalink.oracle.com or phone 1.800.233.1711 for assistance.

Before calling Oracle Support about a problem with an Agile PLM for Process manual, please have the full part number, which is located on the title page.

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Accessibility of Code Examples in Documentation

Screen readers may not always correctly read the code examples in this document. The conventions for writing code require that closing braces should appear on an otherwise empty line; however, some screen readers may not always read a line of text that consists solely of a bracket or brace.

Accessibility of Links to External Web Sites in Documentation

This documentation may contain links to Web sites of other companies or organizations that Oracle does not own or control. Oracle neither evaluates nor makes any representations regarding the accessibility of these Web sites.

Audience

This guide is intended for end users who are responsible for creating and managing information in Agile Product Lifecycle Management for Process. Information about administering the system resides in the *Agile Product Lifecycle Management for Process Administrator User Guide.*

Variability of Installations

Descriptions and illustrations of the Agile PLM for Process user interface included in this manual may not match your installation. The user interface of Agile PLM for Process applications and the features included can vary greatly depending on such variables as:

- Which applications your organization has purchased and installed
- Configuration settings that may turn features off or on
- Customization specific to your organization
- Security settings as they apply to the system and your user account

Where to Find Information

Consult the table below to find specific information from the relevant Agile Product Lifecycle Management for Process information source.

Table 1: Agile Product Lifecycle Management for Process documentation topics, by source

Information type	CACS User Guide	Admin. User Guide	Release Notes	Agile training	Help Desk	Agile sales rep
Administering Agile Product Lifecycle Management for Process		●		●		
Cache management		●				
Compliance	●					
Compliance screening	●					
Core data management		●				
Custom data management		●				
Custom sections		●		●		
Extended attributes	●	●		●		
Feature requests					●	●
Group management		●				
Installing Agile Product Lifecycle Management for Process				●		●
Known issues			●			
New in this release			●	●		●
Printing				●		
Resolved issues			●			

Table 1: Agile Product Lifecycle Management for Process documentation topics, by source (continued)

Information type	CACS User Guide	Admin. User Guide	Release Notes	Agile training	Help Desk	Agile sales rep
System-based roles		●				
Technical support					●	
Using the CACS application	●			●		

Document Conventions

The following formatting elements appear in Agile Product Lifecycle Management for Process documentation.

Element	Meaning
Helvetica Condensed, 9 pt. bold type	A user interface (UI) element that a procedure is instructing you to click, select, or type into. For example, buttons or text entry fields.
`9 pt. monospace font`	Code samples
`10 pt. monospace font`	File names or directory names
Blue italic font	The linked portion of a cross-reference. Click it to go to the referenced heading, table, or figure.
Minion Typeface, Title Case	A named UI element that a procedure is describing but not instructing you to click, select, or type into.
Note Minion 11.5 pt, with faint blue bar over & under	Alerts you to supplemental information.
Caution! Minion 11.5 pt, with faint red bar over & under	Alerts you to possible data loss, breaches of security, or other more serious problems.
Important Minion 11.5 pt, with thick red bar over & under	Alerts you to supplementary information that is essential to the completion of a task.

CHAPTER 1

Introduction

This chapter presents an overview of the Computer Aided Compliance Screening application and describes a few basic features. Topics in this chapter include:

- *Overview*
- *Touch Points with Other Applications*
- *Getting Started with Computer Aided Compliance Screening*

Overview

Computer Aided Compliance Screening (CACS) is a configurable solution in which you can inspect specifications for compliance against any number of user-defined screens. These screens can include several types of constraints and can be nested to enable more complex screening scenarios. You design constraints around compliance standards, usage approval, nutritional attributes, and user defined data that can be captured using extended attributes.

CACS screens can be applied at three levels: raw materials, intermediate materials, and top level materials. The screens are available during the product development lifecycle. This availability can help you achieve early detection of compliance issues.

When running a compliance screen, you obtain feedback on compliance issues through a red/green color code. You can then examine the results to search for the root causes of compliance deviations.

Touch Points with Other Applications

CACS is integrated with several types of specifications in Global Specification Management (GSM).

Global Specification Management

You can run compliance screens against the following specification types in Global Specification Management (GSM):

- Trade specifications
- Menu Item specifications
- Product specifications
- Ingredient specifications

- Formulation specifications
- Packaging material specifications
- Printed packaging specifications

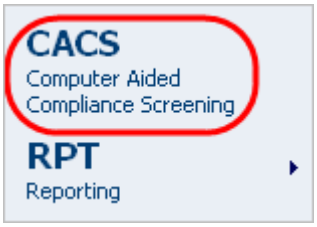
Refer to *Running Screens Against Specifications* on page 2-8, or for more information, see the *Agile Product Lifecycle Management for Process Global Specification Management User Guide*.

Getting Started with Computer Aided Compliance Screening

Accessing CACS

To access the CACS application, select **CACS** from the left navigation panel, shown in figure 1-1 below, or select **CACS** from the Applications top menu bar.

Figure 1-1: Selecting CACS from left navigation panel



For general information on using Agile Product Lifecycle Management for Process software, see the *Agile Product Lifecycle Management for Process Getting Started Guide*.

CHAPTER 2

Using Computer Aided Compliance Screening

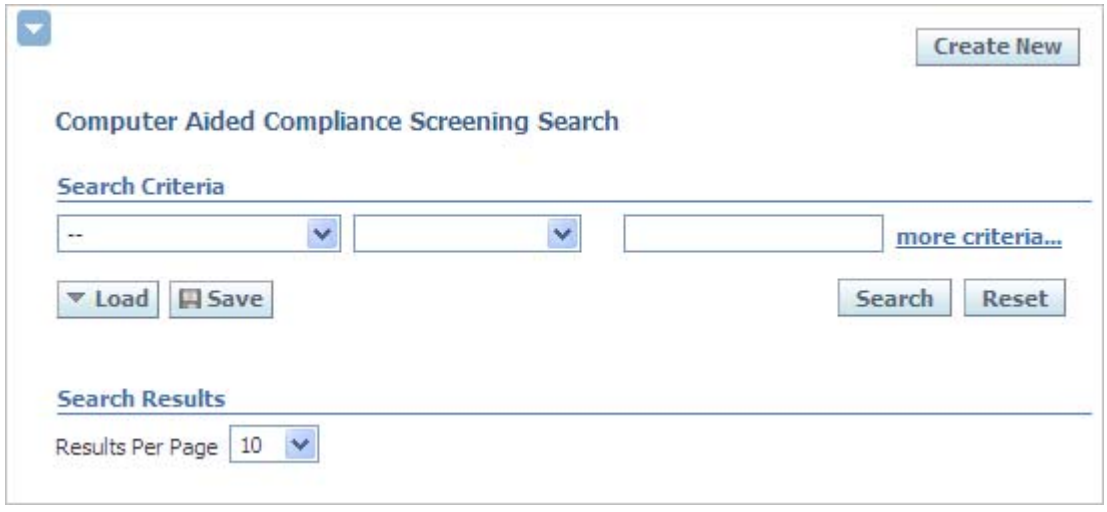
This chapter describes the capabilities and applied uses of the Computer Aided Compliance Screening product. It includes the following topics:

- *Creating a New Compliance Screen*
- *Copying a Compliance Screen*
- *Running Screens Against Specifications*

Creating a New Compliance Screen

Use the Computer Aided Compliance Screening (CACS) application to create and manage compliance screens. To create a new screen, click **Create New** on the search page.

Figure 2-1: Computer Aided Compliance Screening Search page



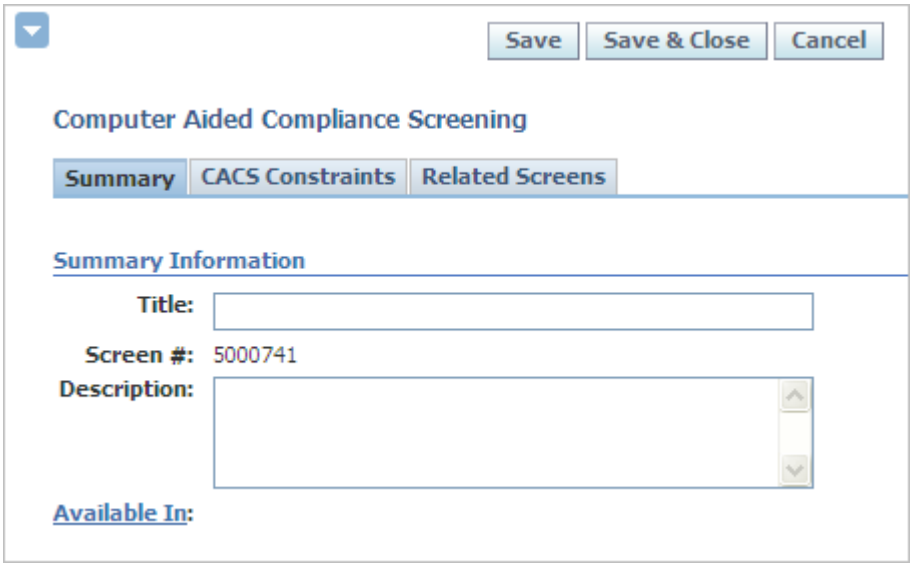
Screens contain three tabs: Summary, CACS Constraints, and Related Screens, shown in figure 2-2 on the next page.

Note The role [SCREEN_CREATOR] is required to create new screens.

Summary Tab

The Summary tab of a CACS screen provides additional information that helps uniquely identify the screen when you are searching using the search form. The tab also identifies where the screen is available to be used for compliance checking in other applications.

Figure 2-2: Summary tab



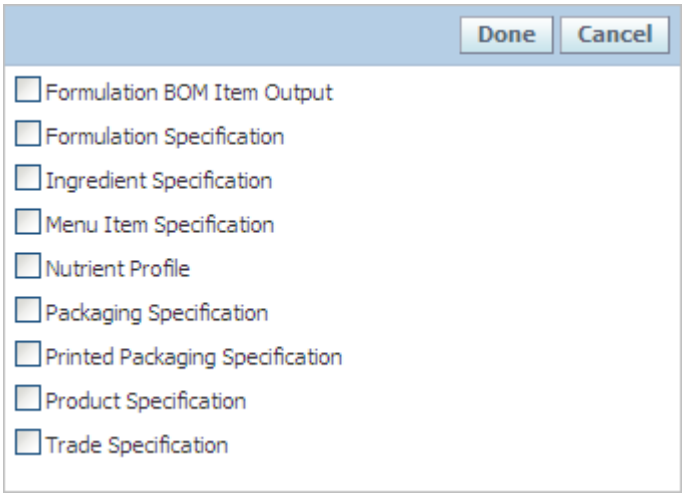
Summary Information Section

The Summary Information section consists of the following fields:

- **Title**—The user-defined title of the screen
- **Screen #**—A system-defined number associated with this screen
- **Description**—The user-defined description of the screen
- **Available In**—The types of objects that are able to use the screen

When you create a new screen, **Title** is the only field required to save the screen. When you click the **Available In** link, a dialog box displays specification types that are able to use the screen, as shown in figure 2-3 below.

Figure 2-3: Objects available for screening



Click the checkboxes to select objects, and then click **Done**. When multiple objects are added using the Available In link, the list of constraints available will be based on the object with the fewest available constraints. For example, if you add ingredients and packaging specifications, you would only have Extended Attribute and Business Unit constraints to define since packaging specifications do not have nutrient or compliance constraints. See *CACS Constraints Tab* on page 2-3 for more information.

Note If the Available In data is not provided, the screen being created will not be available to run against specifications in GSM.

Once you have completed the Summary tab, click the **CACS Constraints** tab.

CACS Constraints Tab

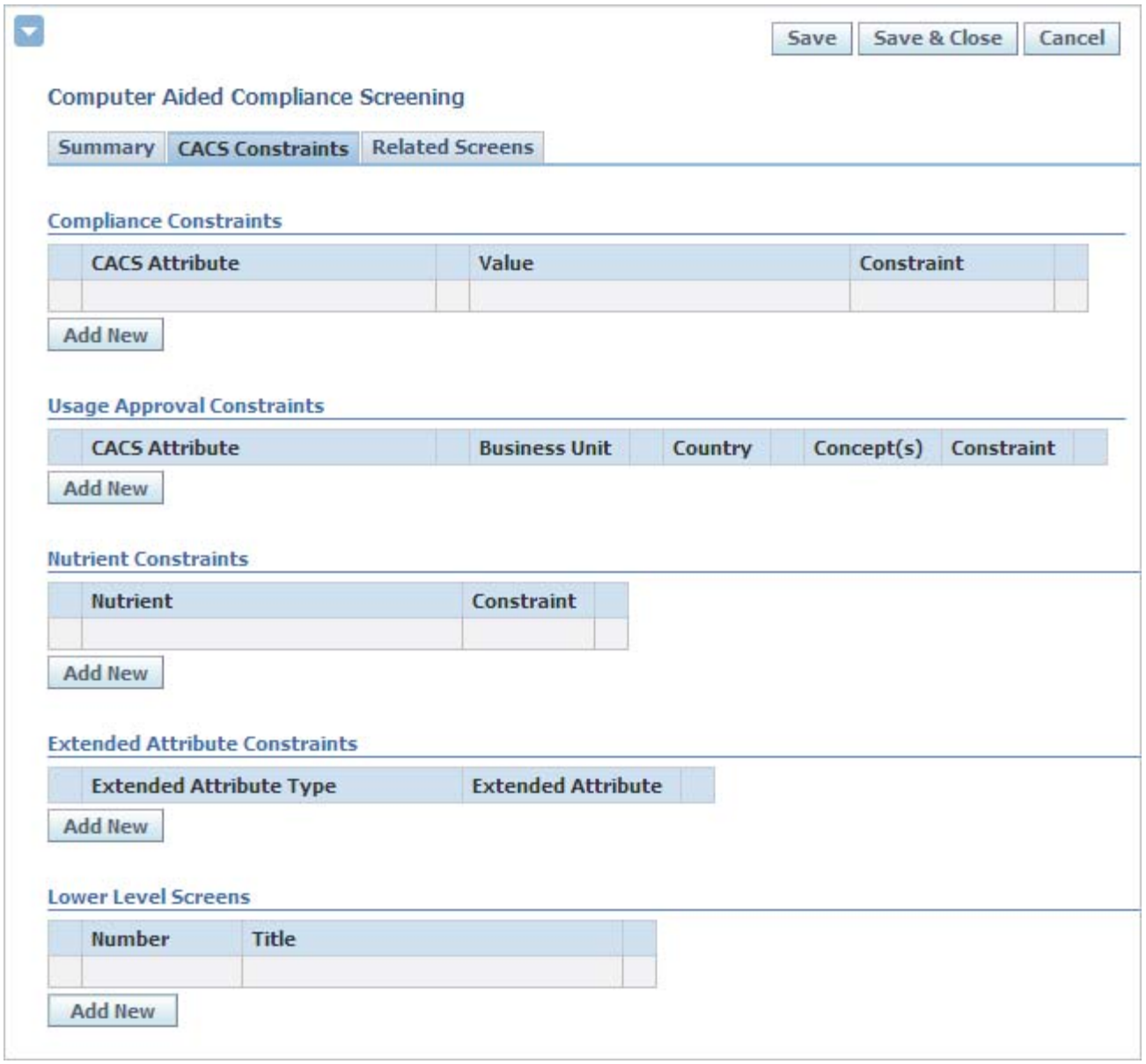
Use the CACS Constraints tab to provide the parameters, or rules, that a specification must comply with in order to pass the screening process.

Build constraints around the following parameters:

- Presence and/or concentration of allergens, additives, and sensitivities (intolerances)
- Country of origin
- General compliance (i.e. kosher, non-GM, organic, vegan, etc.)
- Nutrient levels
- Known usage restrictions (i.e. business unit, country, etc.)
- Custom attributes (using extended attributes)

Figure 2-4 below shows the CACS Constraints tab.

Figure 2-4: CACS Constraints tab



To add a new constraint, identify which type of constraint needs to be added and then click **Add New** under the desired section. Each constraint category has a unique configuration.

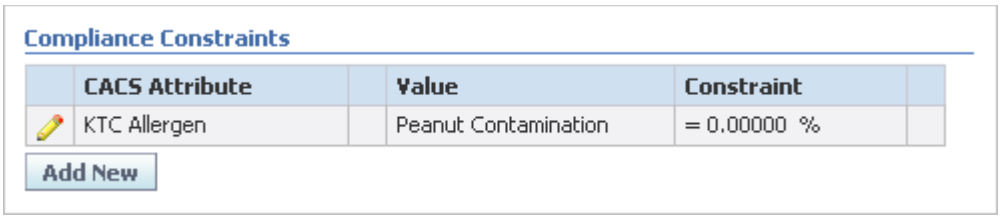
Compliance Constraints Section

For each compliance constraint, do the following:

1. Select a compliance attribute from the CACS Attributes drop-down list.
2. Click the add data icon ( ) to add the value for the attribute in the **Value** field.
3. Set the constraint on the value in the **Constraint** fields.

These actions are reflected below in figure 2-5.

Figure 2-5: Compliance Constraints section



Once you have completed the setup for the constraint, click the apply changes icon ( ) to save the new constraint.

For example, you might want to ensure there is no peanut or peanut oil in your specification. To set up a constraint verifying this, create a screen and add the following constraint:

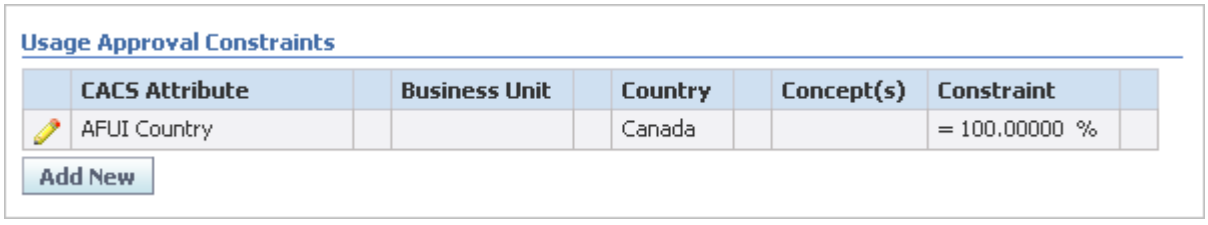
- CACS Attribute—KTC Allergen (Known to Contain Allergen)
- Value—Peanut / Peanut Oil
- Constraint = 0

When a specification is investigated with this screen, if there is any value defined on the specification for Peanut / Peanut Oil other than 0, this constraint would fail.

Usage Approval Constraints Section

As figure 2-6 shows below, for usage approval constraints, you will add a compliance attribute, define some combination of business unit, country, and concept and finally, set the constraint on the value.

Figure 2-6: Usage Approval Constraints section



Once you have completed the setup for the constraint, click the apply changes icon ( ) to save the new constraint.

For example, you might want to make sure that all the specifications in a formulation are approved for use in Canada. To make sure that is the case, create a screen and add the following constraint:

- CACS Attribute—AFUI Country (Approved for Use in Country)
- Country—Canada
- Constraint = 100

When a specification is investigated with this screen, if there is any specification in the formula that is not approved for use in Canada, the constraint would fail.

Nutrient Constraints Section

For nutrient constraints, add a nutrient item and set the constraint on the nutrient, as figure 2-7 shows below.

Figure 2-7: Nutrient Constraints section



Once you have completed the setup for the constraint, select the apply changes icon ( ) to save the new constraint.

For example, you might want to make sure there is at least 10g of Vitamin C in a formula. To ensure that is the case, create a screen and add the following constraint:

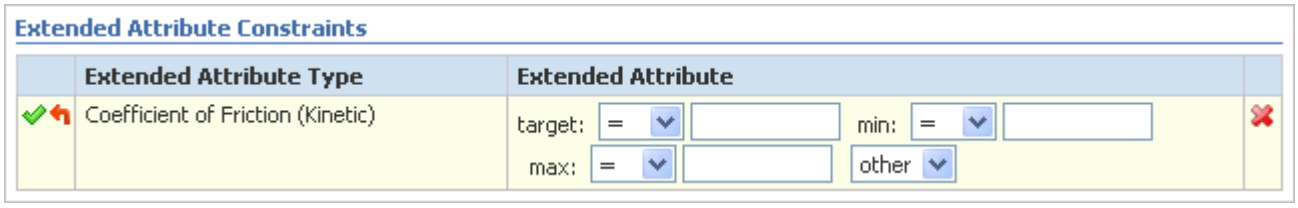
- Nutrient—Vitamin C
- Constraint >= 10g

When a specification is investigated with this screen, if the formula has a Vitamin C content that is less than 10g/100g, the constraint will fail.

Extended Attribute Constraints Section

For extended attribute constraints, add an extended attribute type and set the value on the extended attribute, as figure 2-8 shows below.

Figure 2-8: Extended Attribute Constraints section



Once you have completed the setup for the constraint, click the apply changes icon ( ) to save the new constraint. The constraint varies based on the type of attribute you are using, but the results are returned similarly to all other constraints.

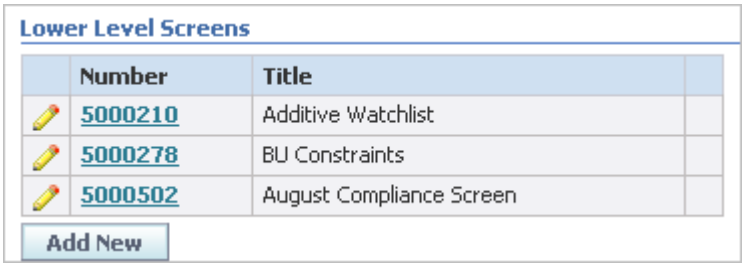
You can add multiple constraints to any given screen.

Note The only extended attributes that are available for screens are those that are marked as distinct and numeric: Numeric, Calculated Numeric, Quantitative Range, and Quantitative Tolerance. For more information, refer to the *Agile Product Lifecycle Management for Process Administrator User Guide*.

Lower Level Screens Section

CACS screens are nested within a given screen to enable you to create complex screening scenarios in a modular way. To link a screen to the screen that you are creating, click **Add New** and use the search page to select the screens that you want to nest. Figure 2-9 on the next page shows the Lower Level Screens section and the **Add New** button.

Figure 2-9: Lower Level Screens section



Note When the screen is investigating a specification, it will return the results for all nested screens at the same time.

Related Screens Tab

The Related Screens tab shows parent screens based on the relationship established in the Lower Level Screens section. When a screen is added as a lower level screen, it displays the specification that it was added to as a parent screen.

Copying a Compliance Screen

Click **Create Copy** from a CACS screen to create a copy of the compliance screen. A new screen number will be assigned and displayed in the Screen # field. All other fields will be copied from the original screen.

Note The role [SCREEN_CREATOR] is required to use the copy feature.

Running Screens Against Specifications

In order to investigate a specification using a compliance screen, you must first select the GSM specification to investigate. Once you access the specification, click the **CACS** tab. This action opens a dialog box that you use to set up the review parameters for screening.

CACS Review Parameters

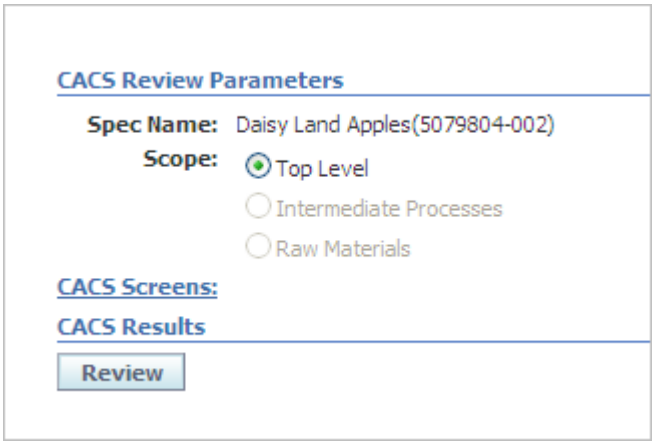
Note The role [COMPLIANCE_REVIEWER] is required to run compliance screens.

CACS review parameters define the rules of investigation for the system. You must select the scope of the investigation and the screens to use. Figure 2-10 below shows the CACS Review Parameters section.

The scope is the level of the hierarchy that you want to run the screens against. The following levels are available:

- **Top Level**—Interrogates the specification that you are currently on.
- **Intermediate Processes**—Interrogates any specifications that are used within the current specification.
- **Raw Materials**—Interrogates the raw materials level of the hierarchy.

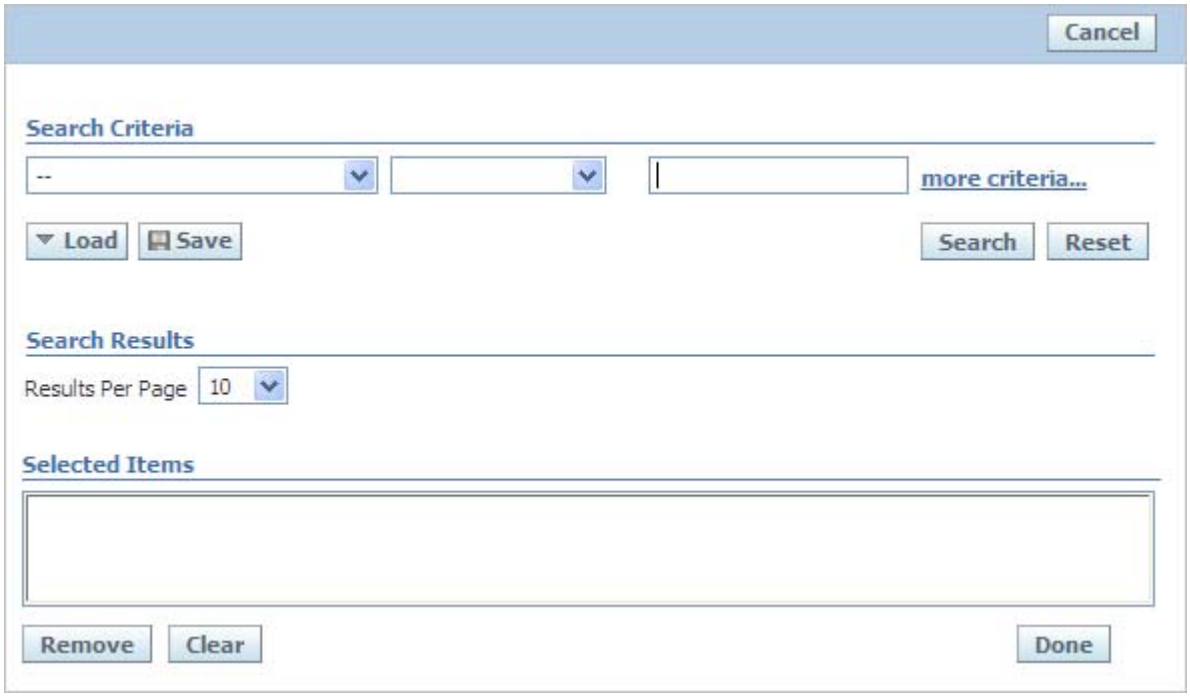
Figure 2-10: CACS Review Parameters section



Note When running nutritional screens on specifications, CACS will only screen the nutrient information on the nutrient profile attached to the top level specification. It is not possible to screen nutritional information on a specification below the top level.

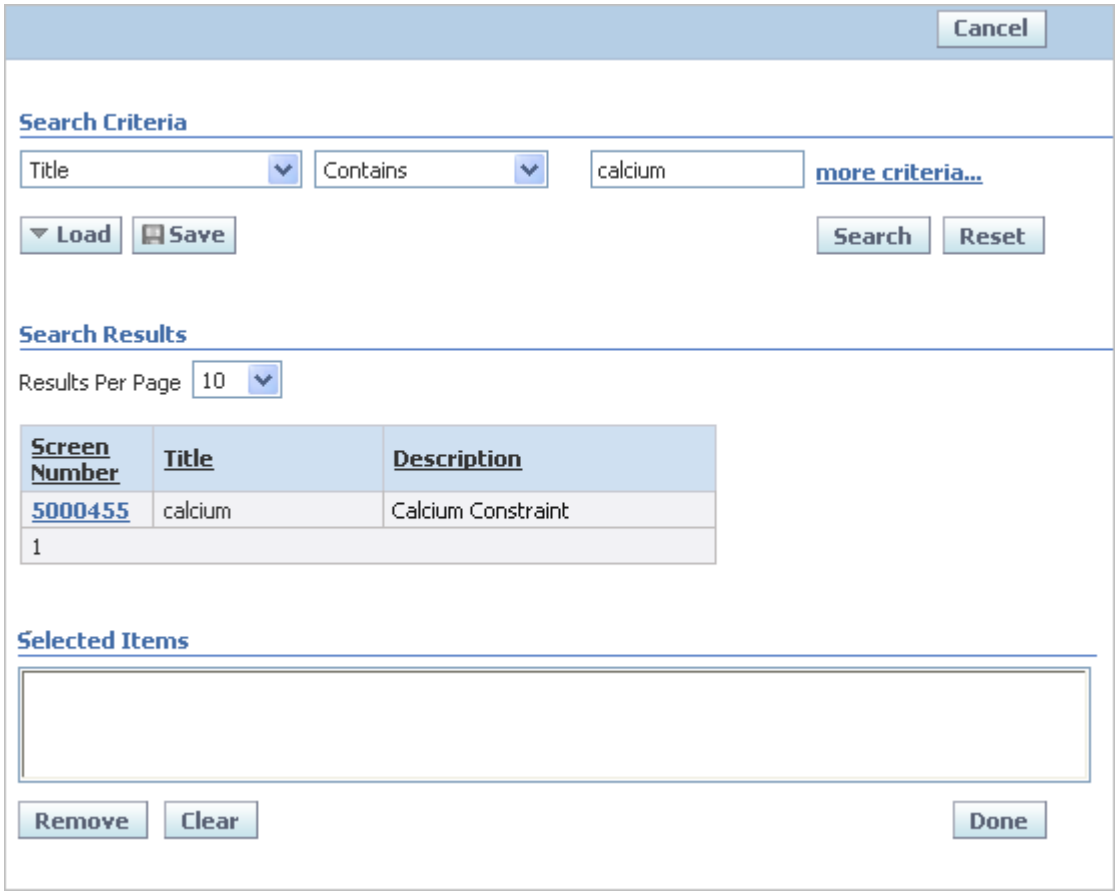
The screens are the previously defined rules that you want to use to determine whether the specifications are in line with the compliance rules. You can add screens to this list by clicking the **CACS Screens** link. The search page is displayed, shown in figure 2-11 below.

Figure 2-11: Search page



Enter search criteria, then click **Search**. The Search Results section lists screens that match the defined criteria, shown in figure 2-12 below.

Figure 2-12: Search results

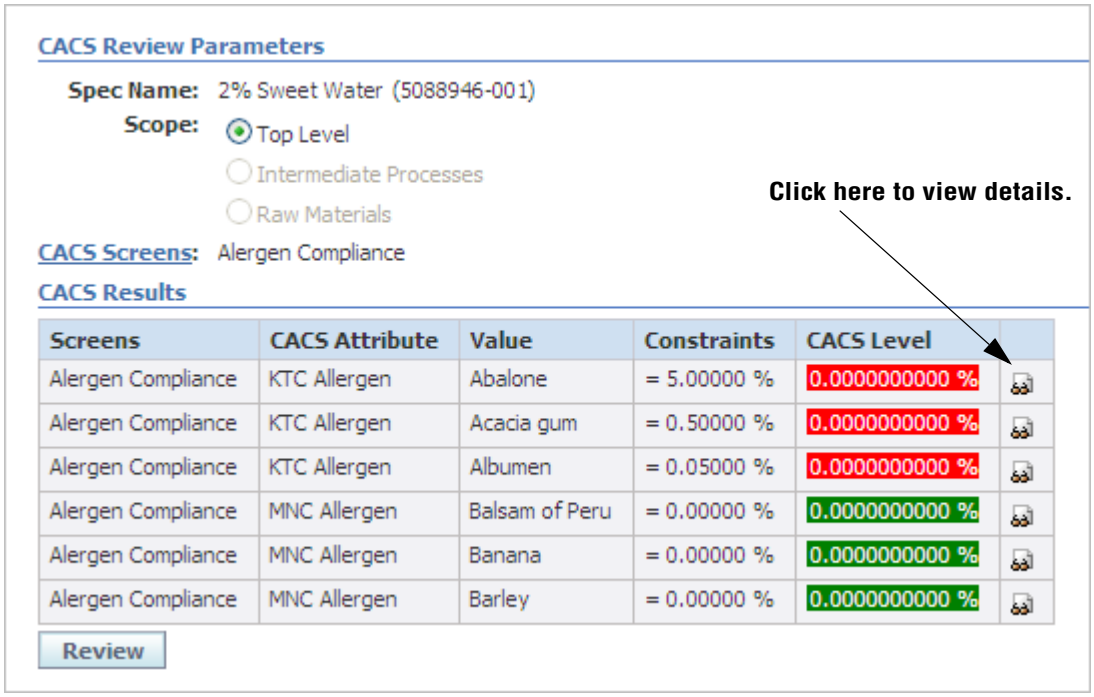


To include screens in the compliance check, click the screen numbers in the Screen Number column. Selected screens display in the Selected Items section.

Once you have selected all the screens to be run, click **Done** to return to the screening page.

To begin the investigation, click **Review**. The results of the screening will be displayed in the CACS Results section, as figure 2-13 shows below.

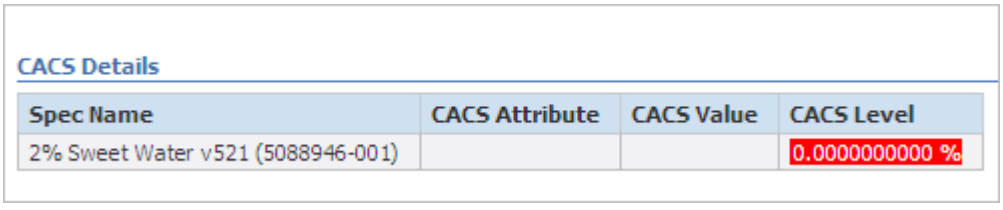
Figure 2-13: CACS Results section



Screen Results and Details

When CACS has finished its review, it will return the results with immediate feedback on compliance issues using a red/green color code. If a constraint has passed, it will be displayed in green. If the constraint has failed, it will be displayed in red. In order to see the details of the constraint results, click the view details icon ( ). When you click the icon, a dialog box will be displayed with the constraint details, as figure 2-14 shows below.

Figure 2-14: CACS Details dialog box



The details contain the specification being screened along with the attribute, value, and levels that were found during investigation of the constraint. This view will help you quickly determine and remedy the root cause of any compliance deviations.