

Oracle® Process Manufacturing

Regulatory Management User's Guide

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Oracle Process Manufacturing Regulatory Management User's Guide, Release 12.1

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Send Us Your Comments

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Oracle welcomes customers' comments and suggestions on the quality and usefulness of this document. Your feedback is important, and helps us to best meet your needs as a user of our products. For example:

- Are the implementation steps correct and complete?
- Did you understand the context of the procedures?
- Did you find any errors in the information?
- Does the structure of the information help you with your tasks?
- Do you need different information or graphics? If so, where, and in what format?
- Are the examples correct? Do you need more examples?

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Note: Before sending us your comments, you might like to check that you have the latest version of the document and if any concerns are already addressed. To do this, access the new Applications Release Online Documentation CD available on My Oracle Support and www.oracle.com. It contains the most current Documentation Library plus all documents revised or released recently.

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Preface

Intended Audience

Welcome to Release 12.1 of the *Oracle Process Manufacturing Regulatory Management User's Guide*.

This guide assumes that you have working knowledge of your business area's processes, tools, principles, and customary practices. It also assumes that you are familiar with Oracle Process Manufacturing. If you have never used Oracle Process Manufacturing, we suggest you attend one or more of the Oracle Process Manufacturing training classes available through Oracle University.

See Related Information Sources on page xi for more Oracle Applications product information.

TTY Relay Access to Oracle Support Services

To reach AT&T Customer Assistants, dial 711 or 1.800.855.2880. An AT&T Customer Assistant will relay information between the customer and Oracle Support Services at 1.800.223.1711. Complete instructions for using the AT&T relay services are available at <http://www.consumer.att.com/relay/tty/standard2.html>. After the AT&T Customer Assistant contacts Oracle Support Services, an Oracle Support Services engineer will handle technical issues and provide customer support according to the Oracle service request process.

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Accessibility of Links to External Web Sites in Documentation

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Structure

1 Regulatory Management Overview

This topic explains setting up regulatory management and the document management process.

2 Document Management

This topic shows how to upload external documents such as Material Safety Data Sheets (MSDS) using Files Approval System. Using Oracle E-Records and setting up Oracle Approvals Management (AME) are also explained.

3 Defining Regulatory Item Information

OPM Regulatory Management Items lets you manage the items that you report hazard information for based on your particular reporting requirements. You can assign hazard information to either products, ingredients, or both.

- The Regulatory Information navigator lets you maintain hazard information for products and ingredients in OPM Regulatory Management. Products and ingredients use those that exist in the Oracle Inventory Item Master.
- The Master Item Association window lets you define and maintain OPM Regulatory Management generic item names and their associated Oracle Inventory item names.

Copy existing items to create new items that are not already defined in OPM Regulatory Management or create new items. You can add, edit, delete, and report on items.

Note: Regulatory Item Information can be viewed from within formulas and recipes. Refer to the *Oracle Process Manufacturing Product*

4 Setting Up Regulatory Management

These topics explain setting up OPM Regulatory Management for reporting product hazard information based on your particular requirements. OPM Regulatory Management lets you manage information to describe qualities and hazards in all supported languages.

5 Managing Hazard Communications

This topic focuses on the processes required for collaborating with Oracle partners to manage hazard communications.

6 Running Regulatory Management Reports

This topic describes the available OPM Regulatory Management reports. Reports are available through the application's Standard Report Submission window. Refer to the *Oracle Applications User's Guide* or the online help topics for detailed information on running reports.

A Navigation Paths

This topic explains typical navigation paths in OPM Regulatory Management.

B Regulatory Management APIs

Glossary

Related Information Sources

Related Guides

Oracle Process Manufacturing shares business and setup information with other Oracle Applications products. Therefore, you may want to refer to other guides when you set up and use Oracle Process Manufacturing. You can read the guides online from the Oracle Applications Document Library CD included in your media pack, or by using a Web browser with a URL that your system administrator provides. If you require printed guides, then you can purchase them from the Oracle Store at <http://oraclestore.oracle.com>

Guides Related to All Products

Oracle Alert User's Guide

This guide explains how to define periodic and event alerts to monitor the status of your Oracle Applications data.

Oracle Applications Concepts

This book is intended for all those planning to deploy Oracle E-Business Suite Release 12, or contemplating significant changes to a configuration. After describing the Oracle Applications architecture and technology stack, it focuses on strategic topics, giving a broad outline of the actions needed to achieve a particular goal, plus the installation and configuration choices that may be available.

Oracle Applications Flexfields Guide

This guide provides flexfields planning, setup, and reference information for the Oracle Applications implementation team, as well as for users responsible for the ongoing maintenance of Oracle Applications product data. This guide also provides information on creating custom reports on flexfields data.

Oracle Application Framework Personalization Guide

This guide covers the design-time and run-time aspects of personalizing applications built with Oracle Application Framework.

Oracle Applications Installation Guide: Using Rapid Install

This book is intended for use by anyone who is responsible for installing or upgrading Oracle Applications. It provides instructions for running Rapid Install either to carry out a fresh installation of Oracle Applications Release 12, or as part of an upgrade from Release 11i to Release 12. The book also describes the steps needed to install the technology stack components only, for the special situations where this is applicable.

Oracle Application Server Adapter for Oracle Applications User's Guide

This guide covers the use of OracleAS Adapter in developing integrations between Oracle applications and trading partners.

Please note that this guide is in the Oracle Application Server 10g (10.1.3.1) Documentation Library.

Oracle Applications System Administrator's Guide Documentation Set

This documentation set provides planning and reference information for the Oracle Applications System Administrator. *Oracle Applications System Administrator's Guide - Configuration* contains information on system configuration steps, including defining concurrent programs and managers, enabling Oracle Applications Manager features, and setting up printers and online help. *Oracle Applications System Administrator's Guide - Maintenance* provides information for frequent tasks such as monitoring your system with Oracle Applications Manager, managing concurrent managers and reports, using diagnostic utilities, managing profile options, and using alerts. *Oracle Applications System Administrator's Guide - Security* describes User Management, data security, function security, auditing, and security configurations.

Oracle Applications User's Guide

This guide explains how to navigate, enter data, query, and run reports using the user interface (UI) of Oracle Applications. This guide also includes information on setting user profiles, as well as running and reviewing concurrent requests.

Oracle e-Commerce Gateway User's Guide

This guide describes the functionality of Oracle e-Commerce Gateway and the necessary setup steps in order for Oracle Applications to conduct business with trading partners through Electronic Data Interchange (EDI). It also contains how to run extract programs for outbound transactions, import programs for inbound transactions, and the relevant reports.

Oracle e-Commerce Gateway Implementation Guide

This guide describes implementation details, highlights additional setups for trading partner, code conversion, and Oracle Applications as well as provides the architecture guidelines for transaction interface files. This guide also contains troubleshooting information and how to customize EDI transactions.

Oracle Report Manager User's Guide

Oracle Report Manager is an online report distribution system that provides a secure and centralized location to produce and manage point-in-time reports. Oracle Report Manager users can be either report producers or report consumers. Use this guide for information on setting up and using Oracle Report Manager.

Oracle iSetup User Guide

This guide describes how to use Oracle iSetup to migrate data between different instances of the Oracle E-Business Suite and generate reports. It also includes configuration information, instance mapping, and seeded templates used for data migration.

Oracle Workflow Administrator's Guide

This guide explains how to complete the setup steps necessary for any product that includes workflow-enabled processes. It also describes how to manage workflow processes and business events using Oracle Applications Manager, how to monitor the progress of runtime workflow processes, and how to administer notifications sent to workflow users.

Oracle Workflow Developer's Guide

This guide explains how to define new workflow business processes and customize existing Oracle Applications-embedded workflow processes. It also describes how to define and customize business events and event subscriptions.

Oracle Workflow User's Guide

This guide describes how users can view and respond to workflow notifications and monitor the progress of their workflow processes.

Oracle Workflow API Reference

This guide describes the APIs provided for developers and administrators to access Oracle Workflow.

Oracle XML Gateway User's Guide

This guide describes Oracle XML Gateway functionality and each component of the Oracle XML Gateway architecture, including Message Designer, Oracle XML Gateway Setup, Execution Engine, Message Queues, and Oracle Transport Agent. The integrations with Oracle Workflow Business Event System and the Business-to-Business transactions are also addressed in this guide.

Oracle XML Publisher Report Designer's Guide

Oracle XML Publisher is a template-based reporting solution that merges XML data with templates in RTF or PDF format to produce a variety of outputs to meet a variety

of business needs. Using Microsoft Word or Adobe Acrobat as the design tool, you can create pixel-perfect reports from the Oracle E-Business Suite. Use this guide to design your report layouts.

Oracle XML Publisher Administration and Developer's Guide

Oracle XML Publisher is a template-based reporting solution that merges XML data with templates in RTF or PDF format to produce a variety of outputs to meet a variety of business needs. Outputs include: PDF, HTML, Excel, RTF, and eText (for EDI and EFT transactions). Oracle XML Publisher can be used to generate reports based on existing E-Business Suite report data, or you can use Oracle XML Publisher's data extraction engine to build your own queries. Oracle XML Publisher also provides a robust set of APIs to manage delivery of your reports via e-mail, fax, secure FTP, printer, WebDav, and more. This guide describes how to set up and administer Oracle XML Publisher as well as how to use the Application Programming Interface to build custom solutions.

Guides Related to This Product

Oracle Process Manufacturing Cost Management User's Guide

The Oracle Process Manufacturing Cost Management application is used by cost accountants to capture and review the manufacturing costs incurred in their process manufacturing businesses. The guide describes how to set up and use this application.

Oracle Process Manufacturing Process Execution User's Guide

The Oracle Process Manufacturing Process Execution application lets you track firm planned orders and production batches from incoming materials through finished goods. Seamlessly integrated to the Product Development application, Process Execution lets you convert firm planned orders to single or multiple production batches, allocate ingredients, record actual ingredient usage, and then complete and close production batches. Production inquiries and preformatted reports help you optimize inventory costs while maintaining a high level of customer satisfaction with on-time delivery of high quality products. The *Oracle Process Manufacturing Process Execution User's Guide* presents overviews of the tasks and responsibilities for the Production Supervisor and the Production Operator. It provides prerequisite setup in other applications, and details the windows, features, and functionality of the application.

Oracle Process Manufacturing Product Development User's Guide

The Oracle Process Manufacturing Product Development application provides features to manage formula, routing, recipe, and validity rule development within process manufacturing operations. Use it to manage multiple laboratory organizations and support varying product lines throughout the enterprise. Characterize and simulate the technical properties of ingredients and their effects on formula performance and cost. Simulate and optimize formulations before beginning expensive laboratory test batches. Product Development coordinates each development function to provide a rapid, enterprise-wide implementation of new products in your plants. The guide describes how to set up and use this application.

Oracle Process Manufacturing Quality Management User's Guide

The Oracle Process Manufacturing Quality Management application provides features to test material sampled from inventory, production, or receipts from external suppliers. The application lets you enter specifications and control their use throughout the enterprise. Customized workflows and electronic recordkeeping automate plans for sampling, testing, and result processing. Compare specifications to assist in regrading items, and match customer specifications. Aggregate test results and print statistical assessments on quality certificates. Run stability testing with unrivaled ease. Several preformatted reports and inquiries help manage quality testing and reporting. The guide describes how to set up and use this application.

System Administration User's Guide

Much of the System Administration duties are performed at the Oracle Applications level, and are therefore described in the Oracle Applications System Administrator's Guide. The *Oracle Process Manufacturing System Administration User's Guide* provides information on the few tasks that are specific to Oracle Process Manufacturing. It offers information on performing Oracle Process Manufacturing file purge and archive, and maintaining such things as responsibilities, units of measure, and organizations.

Regulatory Management User's Guide

Oracle Process Manufacturing Regulatory Management provides solutions for document management that help meet the FDA 21 CFR Part 11 and other international regulatory compliance requirements. Regulatory information management is facilitated by use of electronic signatures. Manage hazard communications by collaborating with Oracle partners to dispatch safety documents, attached printed documentation sets such as the MSDS to shipments, and set up workflows to manage documentation revisions, approvals, and transmittals. The *Oracle Process Manufacturing Regulatory Management User's Guide* provides the information to set up and use the application.

Oracle Manufacturing Execution System for Process Manufacturing

Oracle Manufacturing Execution System (MES) for Process Manufacturing provides a seamless integration to product development and process execution applications for rapid deployment and tracking of procedures, work instruction tasks, and batch records. Set up and manage material dispensing operations and produce electronic batch records interactively with full electronic signature control, nonconformance management, and label printing routines. The *Oracle Manufacturing Execution System for Process Manufacturing User's Guide* delivers the information to set up and use the application.

API User's Guides

Public Application Programming Interfaces (APIs) are available for use with different Oracle Process Manufacturing applications. APIs pass information into and out of the application tables, thereby bypassing the user interface. Use of these APIs is documented in separately available documentation.

Oracle Engineering User's Guide

This guide enables your engineers to utilize the features of Oracle Engineering to quickly introduce and manage new designs into production. Specifically, this guide details how to quickly and accurately define the resources, materials and processes necessary to implement changes in product design.

Oracle Inventory User's Guide

This guide describes how to define items and item information, perform receiving and inventory transactions, maintain cost control, plan items, perform cycle counting and physical inventories, and set up Oracle Inventory.

Oracle Bills of Material User's Guide

This guide describes how to create various bills of material to maximize efficiency, improve quality and lower cost for the most sophisticated manufacturing environments. By detailing integrated product structures and processes, flexible product and process definition, and configuration management, this guide enables you to manage product details within and across multiple manufacturing sites.

Oracle Work in Process User's Guide

This guide describes how Oracle Work in Process provides a complete production management system. Specifically this guide describes how discrete, repetitive, assemble-to-order, project, flow, and mixed manufacturing environments are supported.

Oracle Quality User's Guide

This guide describes how Oracle Quality can be used to meet your quality data collection and analysis needs. This guide also explains how Oracle Quality interfaces with other Oracle Manufacturing applications to provide a closed loop quality control system.

Oracle Shipping Execution User's Guide

This guide describes how to set up Oracle Shipping to process and plan your trips, stops and deliveries, ship confirmation, query shipments, determine freight cost and charges to meet your business needs.

Oracle Purchasing User's Guide

This guide describes how to create and approve purchasing documents, including requisitions, different types of purchase orders, quotations, RFQs, and receipts. This guide also describes how to manage your supply base through agreements, sourcing rules and approved supplier lists. In addition, this guide explains how you can automatically create purchasing documents based on business rules through integration with Oracle Workflow technology, which automates many of the key procurement processes.

Oracle interMedia User's Guide and Reference

This user guide and reference provides information about Oracle interMedia. This product enables Oracle9i to store, manage, and retrieve geographic location information, images, audio, video, or other heterogeneous media data in an integrated fashion with other enterprise information. Oracle Trading Community Architecture

Data Quality Management uses interMedia indexes to facilitate search and matching.

Oracle Self-Service Web Applications Implementation Guide

This manual contains detailed information about the overview and architecture and setup of Oracle Self-Service Web Applications. It also contains an overview of and procedures for using the Web Applications Dictionary.

Installation and System Administration

Oracle Applications Concepts

This guide provides an introduction to the concepts, features, technology stack, architecture, and terminology for Oracle Applications Release 11i. It provides a useful first book to read before an installation of Oracle Applications. This guide also introduces the concepts behind Applications-wide features such as Business Intelligence (BIS), languages and character sets, and Self-Service Web Applications.

Installing Oracle Applications

This guide provides instructions for managing the installation of Oracle Applications products. In Release 11i, much of the installation process is handled using Oracle Rapid Install, which minimizes the time to install Oracle Applications and the Oracle technology stack by automating many of the required steps. This guide contains instructions for using Oracle Rapid Install and lists the tasks you need to perform to finish your installation. You should use this guide in conjunction with individual product user guides and implementation guides.

Upgrading Oracle Applications

Refer to this guide if you are upgrading your Oracle Applications Release 10.7 or Release 11.0 products to Release 11i. This guide describes the upgrade process and lists database and product-specific upgrade tasks. You must be either at Release 10.7 (NCA, SmartClient, or character mode) or Release 11.0, to upgrade to Release 11i. You cannot upgrade to Release 11i directly from releases prior to 10.7.

"About" Document

For information about implementation and user documentation, instructions for applying patches, new and changed setup steps, and descriptions of software updates, refer to the "About" document for your product. "About" documents are available on My Oracle Support for most products beginning with Release 11.5.8.

Maintaining Oracle Applications

Use this guide to help you run the various AD utilities, such as AutoUpgrade, AutoPatch, AD Administration, AD Controller, AD Relink, License Manager, and others. It contains how-to steps, screenshots, and other information that you need to run the AD utilities. This guide also provides information on maintaining the Oracle applications file system and database.

Oracle Applications System Administrator's Guide

This guide provides planning and reference information for the Oracle Applications System Administrator. It contains information on how to define security, customize

menus and online help, and manage concurrent processing.

Oracle Alert User's Guide

This guide explains how to define periodic and event alerts to monitor the status of your Oracle Applications data.

Oracle Applications Developer's Guide

This guide contains the coding standards followed by the Oracle Applications development staff and describes the Oracle Application Object Library components that are needed to implement the Oracle Applications user interface described in the Oracle Applications User Interface Standards for Forms-Based Products. This manual also provides information to help you build your custom Oracle Forms Developer forms so that the forms integrate with Oracle Applications.

Oracle Applications User Interface Standards for Forms-Based Products

This guide contains the user interface (UI) standards followed by the Oracle Applications development staff. It describes the UI for the Oracle Applications products and how to apply this UI to the design of an application built by using Oracle Forms.

Other Implementation Documentation

Oracle Applications Product Update Notes

Use this guide as a reference for upgrading an installation of Oracle Applications. It provides a history of the changes to individual Oracle Applications products between Release 11.0 and Release 11*i*. It includes new features, enhancements, and changes made to database objects, profile options, and seed data for this interval.

Oracle Workflow Administrator's Guide

This guide explains how to complete the setup steps necessary for any Oracle Applications product that includes workflow-enabled processes, as well as how to monitor the progress of runtime workflow processes.

Oracle Workflow Developer's Guide

This guide explains how to define new workflow business processes and customize existing Oracle Applications-embedded workflow processes. It also describes how to define and customize business events and event subscriptions.

Oracle Workflow User's Guide

This guide describes how Oracle Applications users can view and respond to workflow notifications and monitor the progress of their workflow processes. Oracle Workflow API Reference This guide describes the APIs provided for developers and administrators to access Oracle Workflow.

Oracle Applications Flexfields Guide

This guide provides flexfields planning, setup and reference information for the Oracle E-Records implementation team, as well as for users responsible for the ongoing maintenance of Oracle Applications product data. This guide also provides information on creating custom reports on flexfields data.

Oracle eTechnical Reference Manuals

Each eTechnical Reference Manual (eTRM) contains database diagrams and a detailed description of database tables, forms, reports, and programs for a specific Oracle Applications product. This information helps you convert data from your existing applications, integrate Oracle Applications data with non-Oracle applications, and write custom reports for Oracle Applications products. Oracle eTRM is available on My Oracle Support.

Oracle Applications Message Manual

This manual describes all Oracle Applications messages. This manual is available in HTML format on the documentation CD-ROM for Release 11*i*.

Integration Repository

The Oracle Integration Repository is a compilation of information about the service endpoints exposed by the Oracle E-Business Suite of applications. It provides a complete catalog of Oracle E-Business Suite's business service interfaces. The tool lets users easily discover and deploy the appropriate business service interface for integration with any system, application, or business partner.

The Oracle Integration Repository is shipped as part of the E-Business Suite. As your instance is patched, the repository is automatically updated with content appropriate for the precise revisions of interfaces in your environment.

Do Not Use Database Tools to Modify Oracle Applications Data

Oracle **STRONGLY RECOMMENDS** that you never use SQL*Plus, Oracle Data Browser, database triggers, or any other tool to modify Oracle Applications data unless otherwise instructed.

Oracle provides powerful tools you can use to create, store, change, retrieve, and maintain information in an Oracle database. But if you use Oracle tools such as SQL*Plus to modify Oracle Applications data, you risk destroying the integrity of your data and you lose the ability to audit changes to your data.

Because Oracle Applications tables are interrelated, any change you make using an Oracle Applications form can update many tables at once. But when you modify Oracle Applications data using anything other than Oracle Applications, you may change a row in one table without making corresponding changes in related tables. If your tables get out of synchronization with each other, you risk retrieving erroneous information and you risk unpredictable results throughout Oracle Applications.

When you use Oracle Applications to modify your data, Oracle Applications automatically checks that your changes are valid. Oracle Applications also keeps track of who changes information. If you enter information into database tables using database tools, you may store invalid information. You also lose the ability to track who has changed your information because SQL*Plus and other database tools do not keep a

record of changes.

Regulatory Management Overview

This topic explains setting up regulatory management and the document management process.

This chapter covers the following topics:

- Regulatory Management Processes
- Setting Up Regulatory Management

Regulatory Management Processes

Using OPM Regulatory Management, store defined and calculated physical properties like color, boiling point, for inventory items, and upload documents that you are required to provide to customers when you supply hazardous materials. Items that are hazardous are created in Oracle Inventory with the hazardous flag checked. All regulatory management documents are generated by the partner application.

Formula explosions can be printed on documents based on your specifications. Formulas with Production effectivities display all ingredients, and those with regulatory effectivities show only those ingredients that you are required to report. For technical parameters that are mapped to the field names in OPM Regulatory Management, the technical data is also captured in the document generated by the partner application.

Multilingual Support

The OPM Regulatory Management application supports multilingual data. Use any single character set that you require such as Western European or Eastern European. However, if you require multiple character sets, use a common character set, such as the UTF8 character set.

If you are upgrading from Oracle Applications or Oracle Process Manufacturing applications versions prior to release 11*i* and are implementing a different character set, verify that your data is not truncated or corrupted. Generally, text requires more space when it is converted to the UTF8 character set. However, each character set has its own

conversion characteristics.

See: *Oracle Applications Installation Manuals*

Set up the following data in every language that you require:

- Field Names
- Risk and Safety Phrases
- Territory Profiles
- Disclosure Codes

Seed Data

The OPM Regulatory Management application seeds basic information to ease implementation. The following items are seeded:

- Field Names
- Field Name Classes
- Field Name Class Assignments
- Properties
- Territory Profiles
- Risk Phrases
- Safety Phrases
- Disclosure Codes

Setting Up Regulatory Management

Following is the process for setting up Oracle Process Management (OPM) Regulatory Management:

1. Set up organizations, customers, responsibilities, languages, and profile options in Oracle Applications.
2. Set up items in Oracle Inventory.
3. Set up formulas in Formulator.
4. Complete Regulatory Management Setup in order, then Items.

5. Print the Reports.

Document Management

This topic shows how to upload external documents such as Material Safety Data Sheets (MSDS) using Files Approval System. Using Oracle E-Records and setting up Oracle Approvals Management (AME) are also explained.

This chapter covers the following topics:

- Requirements
- Understanding Document Management
- Setting Up Oracle Approvals Management
- Using the Evidence Store
- Uploading Regulatory Documents
- MSDS for Shipping
- Uploading Documents

Requirements

Does OPM Regulatory Management have an approval process for new and updated documents?

OPM Regulatory Management enables both new and updated documents to be uploaded and routed through an approval process before being published or distributed. The approval process supports the entry and management of 21 CFR Part 11 compliant e-signatures. This signature must contain two distinct components. The Oracle E-Business Suite uses the user ID and password for the approval process.

Can regulatory documents be attached to items and shipments?

OPM Regulatory Management stores MSDS and regulatory documents associated to an OPM record in Oracle E-Records which provides full audit trail and CFR compliance tracking. The documents can be sourced internally, or they can be gathered externally

from third party Regulatory providers. Attaching or modifying documents is controlled through iSignatures Files Approval.

Understanding Document Management

Optionally, Oracle Workflow enables regulatory documents to be submitted for approval before they are made available for general distribution. Approvers are defined in Oracle Approval Manager.

Oracle E-Records provides an interface that lets you search and display historical versions of a document. Search by document name, category, author, or status. You can also display user-defined values for each document based on the document category. And, you can search by user-defined values.

You can automatically attach approved regulatory documents to a shipment or manually to any other entity. Only the most recent version of each approved document can be attached to a shipment. View historical versions from the Oracle E-Record Evidence store.

Setting Up Oracle Approvals Management

Oracle Approvals Management is a self-service web application that lets you define business rules governing the process for approving transactions in other Oracle Applications. The purpose of AME is to define approval rules that determine the approval processes for Oracle Applications. Rules are constructed from conditions and approvals.

See: Oracle Approvals Management User's Guide

Create transaction attributes, conditions, approval groups, and approval rules within AME. The appropriate approvers are determined using the document category in iSignatures Files Approval.

Using the Evidence Store

E-records are stored in an evidence store. The evidence store provides a secure storage location and links to transaction windows. You can query the e-records repository using the evidence store. The Evidence Store window is divided into two regions. The top region lets you specify the query criteria and the bottom region shows the results of the query.

See Also

Oracle E-Records Implementation Guide

Uploading Regulatory Documents

Upload external documents using the iSignatures Files Approval. Each document is assigned a category that contains rules for the approval process. Each category has fifteen descriptive flexfield segments used to store information about the documents in that category. This information is stored in the database with the document, and can be used to search for the document.

Following are the four seeded Regulatory MSDS document categories used to determine the appropriate approvers:

- MSDS for a Regulatory Item
- MSDS for an Inventory Item
- MSDS for Shipment
- MSDS for a Recipient

See Also

Oracle Approvals Management User's Guide

Oracle E-Records Implementation Guide

MSDS for Shipping

The MSDS for Shipping lets you automatically or manually attach documents to shipping transactions.

Uploading Documents

Documents can be attached either automatically or manually.

Automatic

Using the Document Management Information in the OPM Regulatory Management responsibility or Files Approval in the iSignature Responsibility, you can upload a document into the FND tables. You must use a seeded or user-defined category for the shipping transactions to automatically print the document. The user defined category user description must contain the word Safety, MSDS, or Hazard.

Refer to the *Oracle E-Records Implementation Guide* for details on uploading a document.

Manual

Documents attached manually to a sales order or shipping transaction using the

Attachment option for the user-defined categories can be enabled on any window. The user defined category user description must contain the word Safety, MSDS, or Hazard.

You can manually attached a document to both the sales order line and the shipping transaction.

Prerequisites

- Set up categories in the FND Categories window in the Applications Developer responsibility.
- Set up the Categories Assignments on the FND Categories window to include the Sales Order and Shipping Transaction windows.
- Run the concurrent programs Listener for Event Q and Listener for Outcome Q for any automatically uploaded documents.

Adding the Regulatory Document Summary API to a Document Set

In order for an uploaded Regulatory document to print with a Shipment, the Regulatory Document Summary API (Concurrent Program) must be added to a Document Set.

In the Shipping Module, the Regulatory Document Summary API is added on the Document Set window for the Usage Ship Confirm. When Ship Confirm is performed, the Regulatory documents is printed.

1. Navigate to the **Order Management Super User, Process Operations (USA)** responsibility.
2. Navigate to **Document Sets** from Setup Documents. The Document Sets window displays.
3. Query for the Document Sets with the usage: Ship Confirm. There can be many Document Sets, but you must choose the set that is used to print documents with a shipment. The query returns existing document sets. Now, add in the documents block.
4. Enter **Sequence** in the serial order.
5. Enter the Application Process Regulatory Management.
6. Enter Report Name Regulatory Document Summary API.
7. Enter Copies as 1. Number of copies required.
8. Save the information.

To attach a document to a sales order line:

1. Navigate to the **Sales Orders** window from the **Order Management** responsibility.
2. Create and save a sales order.
3. Navigate to the Line Items tab.
4. Click the line you want to attach the document to and click the **Attachments** icon. The **Attachments** window displays.
5. Enter a **Sequence** number and select the list of values for the Category. The list of values displays the seeded categories or any user-defined categories containing the words MSDS, Hazard, or Safety.
6. Enter a description and select the **Data Type** of File.
7. Ensure that the **Entity Name** is OM Order Line.
8. Save the attachments. All attached documents are automatically printed with the sales order line.

To attach a document to a shipping transaction:

1. Navigate to the **Shipping Transaction** window from the **Order Management** responsibility.
2. Select an order and click the **Attachments** icon. The **Attachments** window displays.
3. Enter a **Sequence** number and select the list of values for the Category. The list of values displays the seeded categories or any user-defined categories containing the words MSDS, Hazard, or Safety.
4. Enter a description and select the **Data Type** of File.
5. Ensure that the **Entity Name** is WSH Delivery Details.
6. Save the attachments. All attached documents are automatically printed with the shipping transaction.

Defining Regulatory Item Information

OPM Regulatory Management Items lets you manage the items that you report hazard information for based on your particular reporting requirements. You can assign hazard information to either products, ingredients, or both.

- The Regulatory Information navigator lets you maintain hazard information for products and ingredients in OPM Regulatory Management. Products and ingredients use those that exist in the Oracle Inventory Item Master.
- The Master Item Association window lets you define and maintain OPM Regulatory Management generic item names and their associated Oracle Inventory item names.

Copy existing items to create new items that are not already defined in OPM Regulatory Management or create new items. You can add, edit, delete, and report on items.

Note: Regulatory Item Information can be viewed from within formulas and recipes. Refer to the *Oracle Process Manufacturing Product Development User's Guide*.

This chapter covers the following topics:

- Defining Prerequisites
- Finding Regulatory Item Information
- Viewing Regulatory General Item Information for Existing Items
- Viewing Exploded Components
- Viewing Master Item Associations

Defining Prerequisites

Define the following in OPM Regulatory Management Setup before defining items:

- Define languages before defining field names.
See: *Oracle Applications User's Guide*
- Define field name information, including field name class responsibilities, before defining items. Field name information determines the nodes displayed on the Regulatory Information navigator and who has access to those nodes.

Finding Regulatory Item Information

Use the Item Information window to view details for products and ingredients in OPM Regulatory Management.

To find regulatory item information details:

1. Navigate to the **Find Regulatory Item Information Details** window.
2. Query the existing item to view.
3. Select the item to view:
4. Click **Regulatory Item Detail**. The **Regulatory Information** window is displayed with the Item Information navigator active.

Viewing Regulatory General Item Information for Existing Items

Use the Regulatory Information window to define and maintain item hazard information for products and ingredients in Regulatory Management. You can add, edit, delete, and report on items.

Note: Assign responsibilities to the GR_ITEM_GENERAL field name class to allow access to General Item Information on the Item Information navigator. Do not add or delete field names assigned to this field name class because this can cause unpredictable results on the Item Information navigator.

To view general information for existing items:

1. Navigate to the **Find Regulatory Items** window.
2. Perform one of the following:
 - Enter a full or partial item name and click **Find**. All items that match your criteria displays.

- Enter a specific item name.
3. Select the item to view or edit general information for.
 4. Click **Regulatory Item Detail**. The **Regulatory Information** window displays. The field names classes, field names, and properties that you set up display on the navigator. Only field name classes that are assigned to your field name class responsibility are visible. And only field names without explosions for the displayed product class are visible. Edit field name classes, field names, and properties in Setup. You cannot edit them on the navigator.
 5. Click **General Item Information** to complete, view, or edit this information.
 6. View the **Primary CAS** (Chemical Abstracts Service Chemical Registry System) **Number**. The American Chemical Society's Chemical Abstract Service assigns CAS numbers.
 7. View the **Regulatory Item Creator**. Defaults to the name of the user who created the item.
 8. **Item** is the revision number of the item to reflect that changes have been made.
 9. Enter the **Actual Hazard** percentage of the item that is hazardous. The default is 100% when you select the Explode Ingredient check box to break the ingredient into its components. To calculate the percentage from OPM Regulatory Management or OPM Product Development, leave the actual hazard percentage at 100. This is available when the Ingredient check box is selected and the Explode Ingredients check box is cleared. It is unavailable when both Ingredient and Explode Ingredients are selected or both are cleared. Required.

Note: The ingredient is reduced based on this percentage for components that are not 100% hazardous.

10. Select to **Explode Ingredient** into its components. This field is clear if the ingredient is at its lowest level in the formula and is available when the ingredient check box is selected. A formula must exist in either the Formulator or Regulatory Management applications for any ingredient that you plan to explode. Default.

Formulas are exploded based on the recipes and validity rules associated with them. The components are exploded based on the existing active Regulatory or Product Development recipe and validity rules or both. Refer to the *Oracle Process Manufacturing Product Development User's Guide* for details. The validity rule precedence is:

1. Regulatory validity rule for the specific organization

2. Regulatory validity rule with no organization specified
 3. Production validity rule for the specific organization
 4. Production validity rule with no organization specified
11. Select the brackets ([]) to enter descriptive flexfield information.
 12. Save the window.

To open an item:

1. Select **Open Item** from the **Actions** menu. The **Find Regulatory Items** window displays.
2. Select the required item.
3. Click **Regulatory Item Detail**.
4. View the details on the **Regulatory Information** window.

To close an item:

Choose **Close Item** from the **Actions** menu.

To copy an item:

choose **Copy Item** from the **Actions** menu.

To paste an item:

Choose **Paste Item** from the **Actions** menu.

To expand the item node:

Choose **Expand** from the **Actions** menu.

To expand all the information on the item node:

Choose **Expand All** from the **Actions** menu.

To collapse the item node:

Choose **Collapse** from the **Actions** menu.

To collapse all the information on the item node:

Choose **Collapse All** from the **Actions** menu.

Viewing Exploded Components

Exploded components lets you explode items into components based on formulas, recipes, and validity rules. An item must already exist in OPM Regulatory Management before you can enter it as an ingredient item code.

Assign responsibilities to the GR_EXPLOSION field name class and Explosion form block to allow access to Exploded Components Information on the Item Information navigator. You can add field names to this field name class for tracking information. Do not add or delete field names assigned to this field class because it can cause unpredictable results on the Regulatory Information navigator.

Proper access to a formula is defined through Formula Security Profiles. Access to a formula can be defined as view only or view and update.

See: *Oracle Process Manufacturing Product Development User's Guide*

To view the exploded components:

1. Navigate to the **Exploded Components** window.
2. The following fields display:
 - **Ingredient Item Code** is:
 - Disabled if the Formula Source Indicator on the General Item Information window is set to Formula. The formula is exploded in the respective OPM application and displays here.
 - Disabled if the Formula Source Indicator on the General Item Information window is set to No Formula. The item displays at 100%.
 - **Percent** is:
 - Disabled if the Formula Source indicator on the General Item Information window is set to Formula. The percentage for each ingredient in the formula is exploded in the respective OPM application and displayed here.
 - Disabled if the Formula Source indicator on the General Item Information window is set to No Formula. The item displays at 100%.
 - **Refresh Formula Explosion** is available if the Formula Source indicator on the General Item Information window is set to Formula. Click to update the display

to reflect the most current item explosion information from the Formulator application.

Viewing Master Item Associations

Use the Master Item Associations window to view the inventory item links to master regulatory items. You can view on master item associations.

To find master item associations:

1. Navigate to the **Find Master Item Associations** window.
2. Enter the following criteria to search for an item master association:
 - Enter **Regulatory Item** to search for an item master association using the name of the item.
 - Enter **Regulatory Item Description** to search for an item master association using the description of the item.
 - Enter **Inventory Item** to search for an item master association using the associated inventory item.
 - Enter **Inventory Item Description** to search for an item master association using the associated inventory item description.

To enter master item associations:

1. Navigate to the **Master Item Associations** window.
2. Select the **Master Regulatory Item** that identifies the item defined in Regulatory. Required. You can only select existing Regulatory Management Items on the Master Item Associations window. Define items in Regulatory Information on the General Item Information window. The **Description** for the master regulatory item displays.
3. Enter the inventory **Item** from the Inventory Management Item Master that you want to associate with the master regulatory item. Required. The **Description** of the inventory item displays.
4. Select **Use Regulatory Item Description** to display the master regulatory item description for the selected item. Clear to display the inventory item description that you enter for the selected item.
5. Select the brackets ([]) to enter descriptive flexfield information. This descriptive flexfield lets you add your own information to the master regulatory item.

6. Perform one of the following:
 - If **Use Regulatory Item Description** is selected, then go to step 7.
 - If **Use Regulatory Item Description** is cleared, then go to step 4.
7. Select **Item Descriptions** from the **Actions** menu.
8. Enter a valid **Language**. Enter every language that you are creating documents for. Required.
9. Enter an item **Description** in the language selected in the Language field. Required.
10. Select the brackets (**[]**) to enter descriptive flexfield information. This descriptive flexfield lets you add your own information to the master regulatory item.
11. Click **OK**.
12. Save the window

You can use Attachments with this window. Refer to the *Oracle Applications User's Guide* for detailed information on using attachments and folders.

Setting Up Regulatory Management

These topics explain setting up OPM Regulatory Management for reporting product hazard information based on your particular requirements. OPM Regulatory Management lets you manage information to describe qualities and hazards in all supported languages.

This chapter covers the following topics:

- Defining Disclosure Code
- Viewing Properties
- Viewing Field Name Classes
- Defining Field Names
- Editing Field Name Class Assignments
- Viewing Hazard Classification Codes
- Defining Risk Phrase Details
- Defining Safety Phrases Details
- Setting Up Profile Options
- Setting Up Territory Profiles
- Defining Item Relationships
- Editing Organization Items
- Using the Formulator Workbench

Defining Disclosure Code

Use the Disclosure Code Details window to define and maintain logical groupings for items with similar legislative or recipient reporting levels. You can then link these groupings to the appropriate recipients, items, or both. You can add, edit, delete, and report on disclosure codes.

1. Navigate to the **Disclosure Codes** window.
2. Enter the disclosure **Code** that identifies the ingredient exposure reporting levels. Required.
3. Enter the **Description** for the disclosure code. Required.
4. Save the window.

To find disclosure codes:

1. Navigate to the **Find Disclosure Codes** window.
2. Enter the following criteria to narrow your search:
 - **Code** to search for a disclosure code using the code name.
 - **Description** to search for a disclosure code using the code description.
3. Click **Find** to search or Click **New** to enter a new disclosure code.

Viewing Properties

Use the Properties window to view the property IDs and their associated types, descriptions, and values. You can then link these properties to the appropriate field names.

Properties assist in field name maintenance by letting you modify language translations, information, and values as necessary. A basic set of properties is seeded into Regulatory Management. You can view report on property IDs and information.

In addition, properties determine the data entry fields that display for each field name on the Regulatory Information navigator. Properties are assigned to field names before those properties display for the field names on the Regulatory Information navigator.

The following shows the flow of information on the Regulatory Information navigator:

Item Information

- Field Name Classes (primary node). For example, Physical Data.
- Field Name (secondary node). For example, Boiling Range.
- Properties (data entry window). For example, Low Number, High Number, and Scale. Once properties are defined, enter data, such as 200 - 215 Fahrenheit on the properties window.

Prerequisite

Define languages before defining properties.

See: *Oracle Applications User's Guide*

To view properties:

1. Navigate to the **Properties** window.
2. Choose **Find** from the **View** menu.
3. Select the property. The following fields display:
 - **Property Id** is the identification number of the property.
 - **Property Type** is the type of property. Valid values are Flag, Numeric, Alphanumeric, Date, and Phrase.
 - **Length** is the field length of the property.
 - **Precision** is the decimal precision of the field if the property is numeric.
 - **Range Min** is the minimum value for the range of the numeric property.
 - **Range Max** is the maximum value for the range of the numeric property.
 - **Language** is the language in which the property displays.
 - **Property Description** is a brief description of the property. The description displays on the data entry window for the field names that this property is linked to.
 - **Display Order** specifies the order of display if the property is flag.
 - **Value** is the code for the value if the property type is flag.
 - **Value Description** is a brief description of the value if the property type is flag.
4. Close the window.

Viewing Field Name Classes

Use the Field Name Classes window to view the logical groupings of field names that pertain to similar information. You can then link field name classes to the appropriate field names. A basic set of field name classes and field names are seeded into Regulatory Management.

In addition, field name classes and field name class responsibilities determine the primary categories of item information that display on the Item Information navigator. Field name classes are assigned their responsibilities before those field name classes display on the Regulatory Information navigator. All field names assigned to the field name classes that you have field name class responsibilities for, display under those field name classes on the Regulatory Information navigator.

Field Name class responsibilities provide security options for accessing information. You can omit field name classes from group or individual responsibilities to prevent sensitive information from being available to those responsibilities. You can also limit the access that group and individual responsibilities have to a specific field name class on the Regulatory Information navigator. Select the Create check box to create and update information that is linked to the field names within the specific field name class. If you select the Query check box, then you can only view information that is linked to the field names within the specific field name class.

The following shows the flow of information on the Regulatory Information navigator:

Item Information

Field Name Classes (primary node). For example, Physical Data.

Field Name (secondary node). For example, Boiling Range.

Properties (data entry window for secondary node). For example, Low Number, High Number, and Scale. Once properties are defined, you can then enter data, such as 200 - 215 Fahrenheit on the properties window.

Prerequisite

Define languages before defining field name classes.

See: *Oracle Applications User's Guide*

To view field name classes:

1. Navigate to the **Field Name Classes** window.
2. The following information displays:
 - **Field Name** is the name of the field.
 - **Form Block** is the name of the node if a node is created for a field name class in the Regulatory Information navigator. The form block determines which data entry window displays for field names in the specified field name class. When these field names are attached to document structures, the data on the form block is the data that displays in printed documents. Valid values are:
 - Properties: This block is used for Physical Data, Heavy Elements, Transportation, and Additional Item Information. The Properties window

block lets you enter values such as boiling and flash ranges, heavy element concentrations in parts per million, and chemical identification numbers for transport. In addition, you can modify the Properties form block for each field name by adding or deleting properties.

- **Item General** - This form block is used for the General Item Information field name class. The Item General form block lets you enter information such as primary CAS Number, Document Author, Product Class, item versions, and formula source information.
 - **Names** - This form block is used for the Multilingual Descriptions field name class. The Names form block lets you enter Chemical Family, MSDS, Shipping and Trade Names for items in every language.
 - **Explosion** - This form block is used for the Exploded Components field name class. The Explosion form block lets you enter or calculate the ingredients and their concentration percentages for items based on their formula source.
- **Language Description** is a brief description of the language used to describe the field name class.
 - **Field Name Class Description** is a brief description of the field name class. This displays as the primary node on the Regulatory Information navigator.
3. Click **Responsibilities** to access the **Field Name Class Responsibilities** window and view the responsibilities for the field name class.
 4. **Responsibility** is the name of the responsibility that has security access to the field name class. The field name class is then accessible to the person with this responsibility on the Regulatory Information navigator.
 5. **Display Sequence** is the sequence in which the field name class displays in, on the Regulatory Information navigator. For example, a field name class with a display sequence of 10 displays after one with a sequence of 5.
 6. **Create** is selected if the responsibility can query and write access to the field name class. You can then create and update information that is linked to the field names within the specific field name class on the Regulatory Information navigator. Default.
 7. **Query** is selected if the responsibility has query-only access to the field name class. You can then only view information that is linked to the field names within the specific field name class on the Regulatory Information navigator.
 8. Click **OK**.

Defining Field Names

Use the Field Names window to define and maintain the field names. The field names are a grouping of properties used to capture data against an item. Field names are organization specific.

A basic set of field names is seeded into Regulatory Management. You can add, edit, delete, and report on field names. You can enter field names in every language. Enter field names in your base language and all installed languages. Other languages are optional.

In addition, field names determine the secondary categories of item information that display on the Item Information navigator. Define field names and assign them to field name classes before those field names display for the field name classes on the Regulatory Information navigator.

The following shows the flow of information on the Regulatory Information navigator:

Item Information

Field Name Classes (primary node). For example, Physical Data.

Field Name (secondary node). For example, Boiling Range.

Properties (data entry window for secondary node). For example, Low Number, High Number, and Scale. Once properties are defined, you can then enter data, such as 200 - 215 Fahrenheit on the Properties window.

Prerequisites

Define properties before defining field names.

Define languages before defining field names.

See: *Oracle Applications User's Guide*

To define field names:

1. Navigate to the **Field Names** window.
2. Enter the 5-character **Field Name Code**. This is user-definable. The first 2 digits are designated to group related field names together systematically. The last 3 digits of the 5 character numeric code identify the field name. Field names ranging from 001-499 for each section are reserved for system use. You can create field names from the available 500-999 field names for each section. Required.
3. Select a **Field Name Class** from the list. The field name displays under this field name class on the Regulatory Information navigator. Required.

4. Enter the **Safety** category. The safety category identifies the type of safety phrase that is applied for European hazard classifications. For example, when Consumer Use is the selected safety category, the safety phrase "Keep out of reach of children" is applied. The default safety category is "Not used." Required.
5. You can retrieve information from laboratory **Technical Parameters**.
 - Select to retrieve item property information from technical parameters.
 - Clear to avoid retrieving item property information from technical parameters.

To retrieve technical parameter data, create field names. The field name descriptions must match the Technical Parameter Names identically, including case. The appropriate properties are retrieved on the Field Names window and displayed on the Regulatory Information navigator, along with the data from Item Technical Data and, if the technical parameter is linked to a quality test, from quality specifications.

Following are the property values that are retrieved into Regulatory Management:

- The Character data type displays VALUE, HI_CHAR, LW_CHAR, and UNIT properties.
- The Numeric data type displays VALUE, HIGH, LOW, and UNIT properties.
- The Boolean data type displays the VALUE.

Seeded properties to use with the technical parameter data:

- HI_CHAR - The last allowable character in the range, such as Z.
 - LW_CHAR - The first allowable character in the range, such as A.
 - HIGH - The last allowable number in the range, such as 500.
 - LOW - The first allowable number in the range, such as 0.
 - VALUE - The actual character or numeric value, such as RED or 212.
 - UNIT - The unit of measure for the value, such as Fahrenheit or Milliliter.
6. Select the brackets ([]) to enter descriptive flexfield information. This descriptive flexfield lets you add your own information to the field name.
 7. Enter a valid **Language Description**. Base and installed languages required.
 8. Enter a **Field Name Description** in the language selected in the language description. The field name description that you enter displays as a secondary node on the Regulatory Information navigator.

9. If you are entering a heading field name for ingredient information, then the description displays as the heading field name in place of the original field name. Required.
10. Enter a valid **Property ID** for the field name. Property information is not used for ingredient names. They use properties from the base field name. Required.
11. Select **Required** to make the specified property required on the Regulatory Information navigator. For example, for the field name Boiling Range, you can select Required for high number, low number, and scale. Then, those are required fields during data entry. Clear Required to make the specified property not required. Default.
12. View the **Property Type** associated with the selected property.
13. View the **Length** associated with the selected property.
14. View the decimal **Precision** associated with the selected property, if applicable.
15. View the **Range Min** associated with the selected property, if applicable.
16. View the **Range Max** associated with the selected property, if applicable.
17. If you want to exclude field names from one or more product classes, then click **Product Classes** to access the **Field Name Product Class Exclusions** window.
18. Enter the **Product Classes** that you want the field name to be excluded from.
19. Click **OK** to accept the Product Class exclusions and to navigate back to the **Field Names** window.
20. Save the window.

Editing Field Name Class Assignments

Use the Field Name Class Assignments window to display and edit all field name classes assigned to a responsibility and the associated sequence number for display on the navigator.

Note: Field Name Class Assignments can also be viewed and edited from the Field Name Class Responsibilities window.

Prerequisite

Define field name classes.

Define responsibilities.

See: *Oracle Applications User's Guide*

To edit field name class assignments:

1. Navigate to the **Field Name Class Assignments** window.
2. Enter the **Responsibility Name** that you want to view field name class assignments for.
3. View the **Description** for the selected responsibility.
4. View all **Field Name Classes** assigned to the responsibility.
5. View the **Field Name Class Description**. The field name class descriptions display as the primary nodes on the Item Information navigator.
6. View the **Display Order** that the field name class is displayed in on the Regulatory Information navigator. For example, a field name class with a display sequence of 10 displays after one with a sequence of 5.
7. Select **Create** to allow the responsibility query and write access to the field name class. You can then create and update information that is linked to the field names within the specific field name class on the Regulatory Information navigator. Default.
8. Select **Query** to allow the responsibility query-only access to the field name class. You can then only view information that is linked to the field names within the specific field name class on the Regulatory Information navigator.
9. Click the up and down arrows to move the selected **Resequence Display Order**. Save your changes, then click Resequence Display Order to resequence the field name classes so all of the numbers are in sequence. For example, if you move 20 in the current display, which is Multilingual Descriptions, down to 30, then Physical Data is sequenced, and Multilingual Descriptions displays after Physical Data both on the Field Name Class Assignments window and on the Regulatory Information navigator.
10. Save the window.

Viewing Hazard Classification Codes

Hazard classifications let you maintain risk categories for items. Standard hazard classification codes and descriptions are seeded into Regulatory Management. Use the Hazard Classification Codes window to view the hazard classifications.

To view the hazard classification codes:

1. Navigate to the **Hazard Classifications** window.
2. The following field display:
 - **Classification Code** is a code for the classification.
 - **Group Code** is the code for the hazard group.
 - **Language Description** is a brief description of the language.
 - **Hazard Description** is a brief description of the hazard classification in the selected language.
3. Close the window.

To find a hazard classification code:

1. Navigate to the **Find Hazard Classifications** window.
2. Enter the following information to narrow your search:
 - **Classification Code** to search for a hazard classification using its classification code.
 - **Group Code** to search for a hazard classification using its group code.
3. Click **Find**.

Defining Risk Phrase Details

You can add, edit, delete, and report on risk phrases. You can enter risk phrases in every language required on your documents. Enter risk phrases in your base language and all installed languages. Other languages are optional.

To define risk phrase details:

1. Navigate to the **Risk Phrases** window.
2. Enter a risk phrase **Code** or combination. Required.
3. **Additional Information** is used to denote that additional information would be required for a document. Select one of the following:

- None - to indicate that no additional information is required. Default.
 - Temperature
 - Phrase
4. Select the brackets ([]) to enter descriptive flexfield information. This descriptive flexfield lets you add your own information to the Risk Phrases block.
 5. Enter a valid **Language Description**. Base and installed languages required.
 6. Enter the **Phrase Description** in the selected language.
 7. Save the window.

Defining Safety Phrases Details

You can add, edit, delete, and report on safety phrases. You can enter safety phrases in every language required on your documents. Enter safety phrases in your base language and all installed languages. Other languages are optional.

To define safety phrase details:

1. Navigate to the **Safety Phrase** window.
2. Enter a safety phrase **Code** or combination. Required.
3. **Additional Information** is used to denote that additional information would be required for a document. Select one of the following:
 - None - to indicate that no additional information is required. Default.
 - Temperature
 - Phrase

You can enter the specified additional information for risk phrases as phrases on the Phrase Library window. Select the additional risk phrase information in European Data on the Regulatory Information navigator. Required.

4. Select the brackets ([]) to enter descriptive flexfield information. This descriptive flexfield lets you add your own information to the Safety Phrases block.
5. Enter a valid **Language Description**. Base and installed languages required.
6. Enter the **Phrase Description** in the selected language. Required.

7. Save the window.

Setting Up Profile Options

During your implementation, you set a value for selected profile options to specify how your Regulatory Management application controls access to and processes data. Oracle Process Manufacturing (OPM) Regulatory Management uses the listed profile options:

- GR: Document Rebuild Required Workflow Enable
- GR: Sales Order Check for Hazardous Flag
- GR: Partner Application Site ID
- GR: File Exists Action
- GR: Soapaction
- GR: Ws Service Namespace

You can set up these profile options when you set up other applications prior to your OPM Regulatory Management implementation. Refer to the other product user's guides for more details on how these products use these profile options.

Your System Administrator sets user profile options at one or more of the following levels: Site, Application, Responsibility, and User. Use the Personal Profile Options window to view or set your profile options at the user level. Consult your *Oracle Applications System Administrator's Guide* for a list of profile options common to all Oracle Applications.

GR: Document Rebuild Required Workflow Enable

This profile option lets you send a notification to the partner application using the XML Gateway, whenever a regulatory property or a technical parameter of an item is updated.

Default

Null

Options

- Enabled
- Disabled

Recommended Change Level

Site

GR: Default Organization Code

This profile option lets you use the owner organization of formulas, as the default organization, while migrating standalone regulatory formulas to formula, recipe and validity rules windows.

GR: File Exists Action

This profile option lets you check while uploading a document, if there is a regulatory document of the same name existing in the OPM Regulatory Management database.

Default

Dont Overwrite

Options

- Dont Overwrite
- Overwrite
- Version Existing

Recommended Change Level

Site

GR: Partner Application Site ID

This profile option provides the site identification of the partner application, that communicates with OPM Regulatory Management using the XML Gateway.

GR: Sales Order Check for Hazardous Flag

This profile option lets you send a notification to the partner application using the XML Gateway, whenever hazardous material is ordered on a sales order.

Default

Yes

Options

- Yes
- No

Recommended Change Level

Site

GR: Soapaction

This profile option lets you specify the server/address for the Trading Partner soap server service. For example,
<http://xmlns.oracle.com/apps/fnd/XMLGateway/ReceiveDocument>

Default

Null

Recommended Change Level

Site

GR: Ws Service Namespace

This profile option lets you specify the server/address for the Trading Partner web service. For example, <http://xmlns.oracle.com/apps/fnd/XMLGateway>

Default

Null

Recommended Change Level

Site

Setting Up Territory Profiles

The Territory Profiles window lets you set up and maintain defaults for the language, document type, and standard or nonstandard disclosures required for each territory entered. The territory profile is used to determine which document is attached to the shipment line. Add, edit, delete, and report on territory profiles.

Prerequisites

- Define languages.
- Identify the default language, document type, and disclosures required for each territory.

To set up territory profiles:

1. Navigate to the **Territory Profiles** window.
2. Enter the **Territory** code for this profile. The description displays. Required.
3. Enter the **Default Language** to use on documents for the territory entered. The description displays. Required.
4. Enter the **Default Document** to send for the territory entered. The description displays. Required.
5. Enter the **Disclosure** code required for the territory entered. The code determines the ingredient reporting levels for the territory. The description displays. Required.

Defining Item Relationships

Use the Item Relationships window to define the regulatory relationships between the inventory items in your organization.

Refer to the *Oracle Inventory Management User's Guide* for more information.

Editing Organization Items

Use the **Organization Item** window to view and edit the inventory items in your organization.

Refer to the *Oracle Inventory Management User's Guide* for more information.

Using the Formulator Workbench

Use the Formulator of the Oracle Process Manufacturing Product Development to view the formula details.

Refer to the *Oracle Process Manufacturing New product Development User's Guide* for more details.

Managing Hazard Communications

This topic focuses on the processes required for collaborating with Oracle partners to manage hazard communications.

This chapter covers the following topics:

- Managing Chemical Hazard Safety Documentation
- Processing New and Updated Safety Documentation
- Dispatching a Safety Document From an Oracle Partner
- Dispatching a Safety Document Internally
- Attaching and Printing Safety Documents with Shipments
- Setting Up Transaction Types in the XML Gateway
- Understanding OPM Hazard Communication Workflows
- Setting Up OPM Hazard Communication Workflows
- Understanding OPM Hazard Communication XML Messages
- Entering the Dispatch History
- Finding a Dispatch History Record

Managing Chemical Hazard Safety Documentation

To provide full compliance with international safety standards, Oracle offers a hazard communications open interface that lets companies use their existing hazard communication solution with the Oracle E-Business Suite. Several Oracle partners specialize in safety document authoring, management, and distribution to provide the tools, configurable business rules, and expertise on the most recent hazardous materials regulations.

Oracle provides the content for items and formulas. Oracle partners re-create the formula, evaluate its contents using sophisticated rules engines, and produce the Material Safety Data Sheet (MSDS) documentation that is:

- Distributed directly from a partner application
- Uploaded for distribution with Oracle shipping and transportation documents

Oracle helps companies meet safety compliance with "employee right to know" legislation about toxic chemicals in the workplace by ensuring that chemical hazards are properly evaluated, and that information concerning these hazards is transmitted to appropriate employees. Safety documents are included with production batches or any other processes where hazardous material storage and handling documentation is required. Oracle E-Records is used to upload files and send them to a set of defined approvers for an e-signature.

Oracle offers these business solutions to help manage chemical hazard safety documentation:

- Author safety documents in an Oracle partner application using data from the Oracle E-Business Suite.
- Attach safety documents or labels that were authored in an Oracle partner application to objects within the Oracle E-Business Suite.
- Synchronize hazard communication data between Oracle partners and the Oracle E-Business Suite.
- Keep a history of safety hazard communication documents dispatched within the Oracle E-Business Suite, regardless of where, or from which system the dispatch originated.

Understanding Chemical Hazard Regulations

Regulations governing chemical hazard communication are extensive. Hazard communication documentation is required by law in many nations. These requirements are supranational because they transcend governmental boundaries, authorities, and the interests of regulatory bodies.

Widely recognized chemical hazard regulations include:

- Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (HCS), Subpart Z, Toxic and Hazardous Substances (29 CFR 1910.1200)
- Workplace Hazardous Material Information System (WHMIS) in Canada
- Directives published by the European Union and enacted into national law by its member states:
 - Dangerous Substance Directive (67/548/EEC)
 - Dangerous Preparation Directive (1999/45/EC)

- Safety Data Sheet Directive (91/155/EEC)

Hazard communications are typically required by manufacturers in the chemicals, pharmaceutical, pulp and paper, textile, and food and beverage industries.

Producing Compliant Hazardous Material Documentation

Software tools and hazard communication vendor services help author, manage, and distribute safety documents, labels, and other regulated documents. Many of these are required under OSHA, EU Directives, and various regulatory bodies worldwide. This includes the shipment of hazardous materials, information provided to emergency response centers in their evaluation of personal injury resulting from exposure to a hazardous material, proper handling of hazardous material in the workplace, storage and cleanup of hazardous material spills, and audits by regulatory agencies.

Safety documents provide valuable details of material dangers, as well as proper storage, use and handling of a material. The document is prepared in accordance with OSHA Hazard Communications regulations in 29 CFR Part 1910.1200, European regulations in directive 91/155/EC, or Canadian regulations such as WHMIS.

Generating Safety Labels

Another important regulation from the OSHA Hazard Communications Standards (HCS) is the requirement for Employers to ensure that containers of hazardous chemicals have an appropriate warning label.

Much of the data necessary for generating these labels are available from Oracle, such as pertinent ingredients, chemical composition, hazardous materials properties and values. If this data is stored with the regulatory item, then custom reports are written to create the necessary labels. Oracle XML Publisher is one reporting option, although any report writer that can connect to the applications database suffices.

Alternatively, label design and printing facilities are available through partner applications that specialize in hazardous materials management and communication.

Producing New Product Safety Documentation

During the design and development of a new product, several safety-related documents can be required including:

- Safety Data Sheets
- Technical Data Sheet
- Internal Plant Instructions
- Labels

When a formula is created for a new product, essential material safety information is exported to a partner application where these safety-related documents are created and printed.

Customer requirements mandate the limits of certain substances used in the product formulation. OPM Product Development offers tools that can help chemists and formulators reduce uncertainty about the composition of a formula. The Product Development Simulator lets you see the impact of different ingredients on total product output. The full formula explosion is evaluated for contributing substance quantities. You can substitute items, and you can run laboratory batch simulations using actual lots and quality results. In addition, the Optimizer enables you to specify product targets and find the best mix of ingredients based on the formulation entered.

Item Technical Data is used to track chemical composition of items and lots used as ingredients. Item Technical Data enable the Product Development Simulator to evaluate the hazardous material content in a product. A complete formula explosion is performed to examine formula contents at each level. All chemical attributes are reported based on the formula.

Creating and Distributing the Safety Data Sheet

A new safety data sheet is required when a new product is developed that contains hazardous material. A new safety data sheet version is required when hazard information for an existing product changes significantly such as through a new or updated formulation.

When either of these business events occurs in the OPM Product Development application, a workflow triggers to inform the Regulatory Document Manager, or other appropriate individual to generate a new or revised safety data sheet. The business event also exports XML data based on an industry standard safety data sheet Document Type Definition (DTD). The item, chemical information, and formula are available to any application for use as a basis for the new or revised safety data sheet. When an current safety document is available, its distribution is managed by Oracle or one of its partner applications, depending upon the implementation. Ideally, a safety data sheet for each ingredient or product that requires one is stored in the individual application. This safety data sheet becomes available to any business event that requires this safety data information.

Managing Changes to Product Formulations

Whenever a new ingredient is added to or substituted in a formula that contains a hazardous material, the composition of the finished product changes. Perform a formula analysis to evaluate the impact of the product change in the manufacturing process and quality testing. If the product composition changes, then a new or revised safety data sheet must be generated to reflect the new material composition, hazardous material distributors must send updated safety data sheet documentation immediately to material recipients.

Shipping and Transporting Hazardous Materials

Suppliers must send a properly completed safety data sheet at the first shipment of a hazardous material, or with a shipment that follows updating of the safety data sheet with new or significant hazard information.

Safety documents that are stored in the database are attached automatically to sales orders and shipments each time an item is ordered. This is accomplished by defining document attachment rules in Oracle Order Management, or by letting the application find an appropriate safety document that are attached to the shipment document set. An outbound message is sent to the Oracle partner application to determine whether a new or existing safety document must be associated to an order line. When a shipment is created for this item, the appropriate document is attached. Adding the Regulatory Shipping report to the Ship Confirm Document Set ensures that safety data sheets associated with the shipment are printed as a standard part of the Ship Confirm process.

An optional check of the dispatch history for each customer determines whether the customer already received the most recent safety data sheet. This avoids replicate communication of the same information.

Storing, Approving, and Accessing Safety Documentation

Material Safety Data Sheets, Technical Data sheets, Hazard Labels, Internal Plant Instructions, and similar documentation are an integral part of proper material handling processes including storage, production, and shipping of these materials. Oracle uses a 21 CFR Part 11-compliant file approval process that enables the upload of any type of file to the database, and routes it for e-signature approval to a configurable list of reviewers and approvers.

The application captures electronic signatures, enforces file version control, tracks an audit trail of the version history of the file, secures the file based on its status and associates multiple attributes to the file, including associating documents throughout the Oracle E-Business Suite.

Distributing Updated Safety Documentation

Manufacturers and distributors must provide an safety data sheet any time a significant change is made. If a document already exists and an updated document is created, then document distribution must be executed and a dispatch history recorded. This process is managed by a partner application.

Storing and Accessing Current Safety Data Sheets

Requirement: 29 CFR Part 1910.1200(b)(3)(ii) states that "Employers shall maintain any material safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible during each workshift to

laboratory employees when they are in their work areas."

Oracle provides a document repository for the storage of and rapid access to any documents received. Documents are associated with items, formulas, recipes, and batches, or they be cataloged in the document repository that provides a simple search mechanism for rapid retrieval and inspection.

Displaying Regulatory Items and Properties

The Regulatory Item navigator displays regulatory items with a list of their properties categorized and sorted by safety data sheet section. For example, when hydrochloric acid is defined as a regulatory item, its physical properties include its physical state, color, solubility, molecular weight, and specific gravity. The navigator has categories for volatility, ecological impact factors, and transportation requirements. These properties displayed in an expandable treelike framework. One or more inventory items are associated with a regulatory item to reduce setup time. This is helpful when several products all contain the same hazardous substance.

Processing New and Updated Safety Documentation

Creation or revision of formulas or items in the E-Business Suite database triggers a series of workflow-driven events that manage changes to hazard communication documentation.

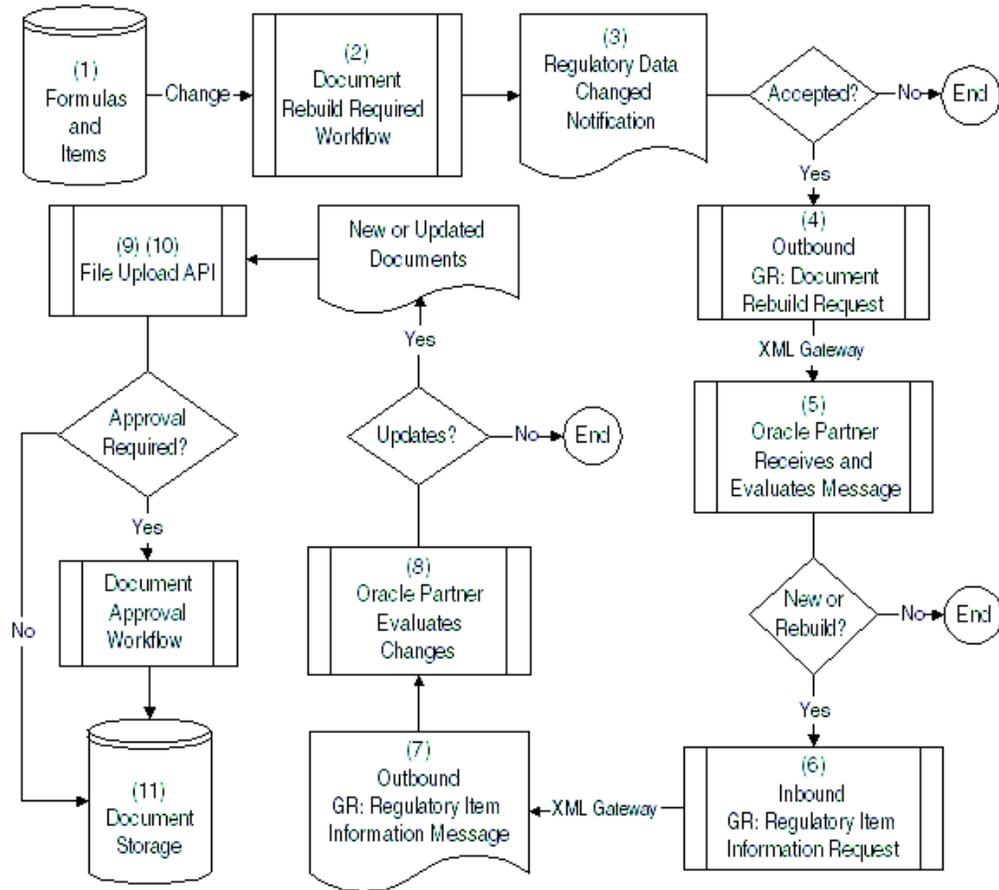
Following summarizes the steps and presents an illustration of this process:

Formulas and items reside in the Oracle database.

1. Changes to formula details such as products, recipe validity rules, and individual ingredient quantities, or changes to regulatory item properties trigger the Document Rebuild Required workflow.
2. The Document Rebuild Required workflow generates a Regulatory Data Changed Notification for item or formula detail changes.
3. Acceptance of the workflow notification sends the outbound GR: Document Rebuild Request message through the XML Gateway.
4. The Oracle partner application receives the message and evaluates whether a new document or document rebuild is required.
5. If either a new document or a document rebuild is required, then the partner application sends the inbound GR: Regulatory Item Information Request message through the XML Gateway using the Regulatory Item Information Request workflow.
6. The XML Gateway receives this message and sends the outbound GR: Regulatory Item Information message that includes all necessary item and formula data.

7. The Oracle partner evaluates the changes and generates any required updates to the documentation.
8. If document approval is required, then the File Upload API triggers an optional Document Approval workflow.
9. New or updated documents are uploaded to the Oracle database using the File Upload API.
10. Approved documents are output as needed from the database. Optionally, they are distributed with shipping documents as described in "Attaching and Printing Regulatory Documents with Shipments." The Dispatch History is updated for each transaction.

This graphic summarizes the previous process:



Dispatching a Safety Document From an Oracle Partner

An Oracle partner can dispatch a safety document to a customer. This event writes a record to the Dispatch History table. The history is retained as a printable document.

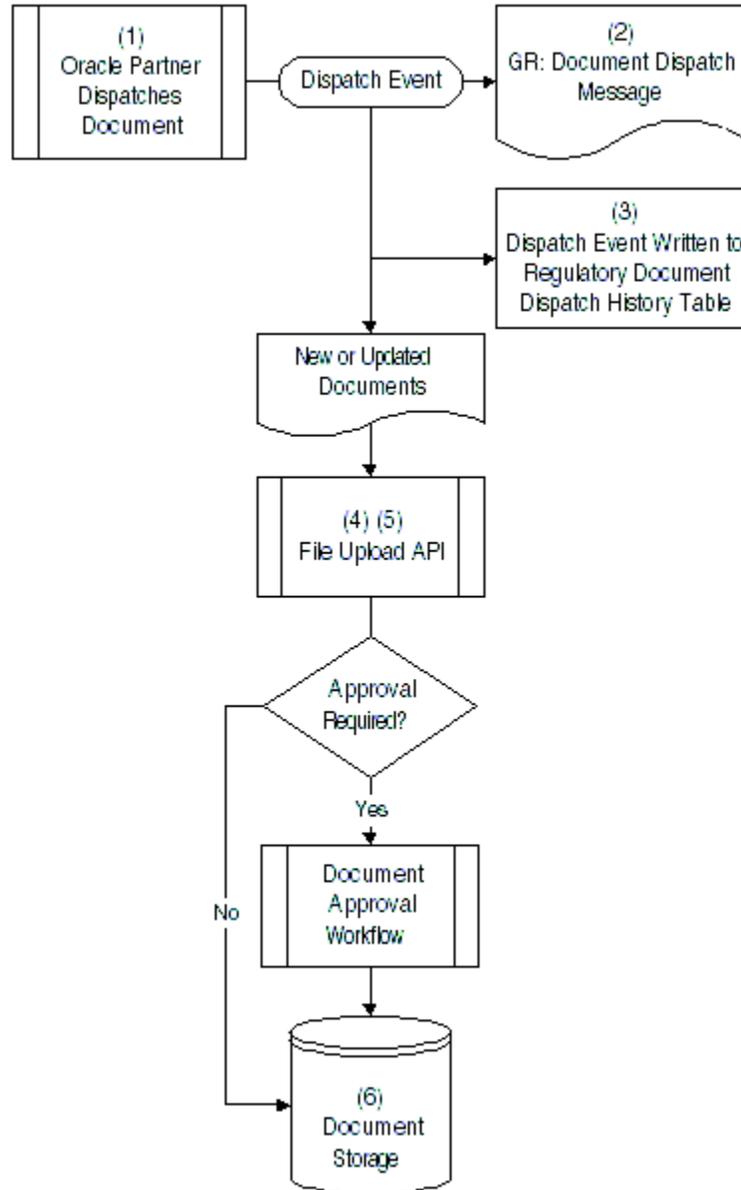
Following summarizes the steps and presents an illustration of this process:

The Oracle partner dispatches a safety document.

1. The dispatch event sends the GR: Document Dispatch message using the XML Gateway.
2. New or updated documents are uploaded to the Oracle database using the File Upload API.
3. The dispatch event is written to the Regulatory Document Dispatch History table where the document is available for viewing on the Dispatch History window.
4. If document approval is required, then the File Upload API triggers an optional Document Approval workflow.

5. Approved documents are output as needed from the database. Optionally, they are distributed with shipping documents as described in "Attaching and Printing Regulatory Documents with Shipments." The Dispatch History window is updated for each transaction.

This graphic summarizes the previous process:



Dispatching a Safety Document Internally

You can dispatch a safety document internally and send a dispatch message using the XML Gateway.

Following summarizes the steps of this process:

A safety document is dispatched internally by Running the Print Regulatory Item concurrent request with Create Dispatch History set to Yes. Manual creation of a record on the Document Dispatch History window.

The dispatch event sends the GR: Document Dispatch History outbound message using the XML Gateway.

Attaching and Printing Safety Documents with Shipments

The request for a safety shipping document print set initiates a series of events that generate and attach appropriate safety documentation to shipments.

Following summarizes the steps of this process:

A sales order is created with a regulatory item.

1. The sales order is pick released.
2. Choose Print Doc Set on the Shipping Transactions window. The Regulatory Document Print API is called as part of the document print request to:
 - Determine if a safety document must be attached to each regulatory item shipment line.
 - Print all documents attached to sales orders or shipment lines.
3. View the Attachments window to display the list of all attached documents.
4. A record is written to the Document Dispatch History window for each safety document printed.

Setting Up Transaction Types in the XML Gateway

Refer to the *Oracle XML Gateway User's Guide* for additional information on setting up transaction types.

1. Define these XML Gateway-related profile options:
 - ECX: Log File Path is the log file path where the XML messages and runtime log are stored.
 - ECX: XSLT File Path is the path where XSLT style sheets are stored.
 - ECX: System Administrator Email Address is the e-mail address for the XML Gateway System Administrator.
 - ECX_OAG_LOGICALID is the sender's information system identifier.

- ECX: Server Time Zone is the time zone where the database server is operating.
2. Define the UTL_FILE_DIR Parameter in the INIT.ORA file.
 3. Enter Trading Partner information. Enable the following transaction types for the Trading Partner:
 - Type: GR, Subtype: GRRRO, GR: Document Rebuild Required (Outbound)
 - Type: GR, Subtype: GRIOO, GR: Regulatory Item Ordered (Outbound)
 - Type: GR, Subtype: GRDDO, GR: Document Dispatch History (Outbound)
 - Type: GR, Subtype: GRIIO, GR: Regulatory Item Information (Outbound)
 - Type: GR, Subtype: GRIRI, GR: Regulatory Item Information Request (Inbound)
 - Type: GR, Subtype: GRPCI, GR: Regulatory Property Change (Inbound)
 - Type: GR, Subtype: GRDDI, GR: Document Dispatch (Inbound)

Refer to "Understanding OPM Hazard Communication XML Messages" for detailed explanations of these transaction types.
 4. Set up these profile options:
 - Set GR: Sales Order Check for Hazards to Yes.
 - Set GR: Document Rebuild Required to Enabled.
 - Set GR: Partner Application Site ID to a value equal to the site used in the Trading Partner setup.
 - Set GR: Soapaction to Yes.
 - Set GR: Ws Service Namespace to Yes.

Understanding OPM Hazard Communication Workflows

This topic introduces you to the concept of a workflow process and refers you to the documentation that fully explains Oracle workflows. It presents an understanding of the OPM Hazard Communication workflows, how to set them up, how to start them, and how to use their windows.

Technical Overview

OPM Hazard Communication workflows use two major components:

- Oracle Workflow
- Oracle Workflow Business Event Systems

Oracle Workflow supports business process definitions to route hazard communications. Each workflow has a rules-based engine that resides in the database. Oracle Workflow routes summary and detail information to each decision maker in the workflow process.

The Oracle Workflow Business Event System defines key business events and associates each of these events to a subscription. The subscription initiates a designated workflow to perform the required database changes, to issue notifications, and to manage the hazard communications process. Events and subscriptions are enabled or disabled as needed using the business event system. You can add a new subscription to an event to perform customized actions.

Understanding Workflow Processes

Oracle Workflow lets you automate and continuously improve business processes by routing information according to a set of business rules. Transmit this information to individuals both inside and outside your enterprise on an individual basis.

Refer to the *Oracle Workflow Guide* and the *Oracle E-Records Implementation Guide* for additional information on:

- Workflow Business Event System
- XML Gateway
- Oracle Approval Management Engine (AME)
- Workflow Notification Subsystem
- Workflow Automatic Notification Processing

OPM Hazard Communication Workflows

Document Rebuild Required Workflow

The Document Rebuild Required workflow generates the Regulatory Data Changed Notification. If the Notification is accepted, then the workflow generates the GR: Document Rebuild Required XML (Outbound) message.

Regulatory Item Information Request Workflow

The Regulatory Item Information Request Inbound event initiates the Regulatory Item Information Request workflow. If the notification is accepted, then the workflow generates the GR: Regulatory Item Information (Outbound) XML Message.

Partner Application Data Change Workflow

The Partner Application Data Change workflow generates the Partner Application Data Change Notification to notify the Regulatory Document Manager of a data change at the partner application.

Document Approval Workflow

Refer to the *Oracle E-Records Implementation Guide* for a description of the process to upload external documents using the iSignatures Files Approval.

Setting Up OPM Hazard Communication Workflows

For the proper functioning of the workflows, a few administrative steps must be handled. These include setting up notification contacts for the workflow and starting the workflow engine.

Document Rebuild Required Workflow

The OPM Document Rebuild Required workflow notifies the workflow recipient of the need to rebuild a safety document. The workflow is instantiated by the person who makes a change to an item, formula, technical parameter, or recipe validity rule.

Setting Up the Document Rebuild Required Workflow

Set up the Document Rebuild Required workflow as follows:

1. Verify that these profile options are set up:
 - Set GR: Sales Order Check for Hazards to Yes.
 - Set GR: Document Rebuild Required to Enabled.
2. Enable the Hazard Communication Outbound Information event.
3. Enable the subscription to the event.
4. Set up AME rules for the event.

Hazard Communication Outbound Information Event

This business event is triggered from a change to a regulatory item property, formula detail, technical parameter, or recipe validity rule.

Event Name

oracle.apps.gr.message.send

Subscriber

Subscriber Workflow:

Hazard Communication Outbound Information

Oracle Approval Management Transaction Name:

Regulatory Document Manager, oracle.apps.gr.reg.documentmanager

Recommended Attributes for Approval Configuration

Parameter	Description
ITEM_NO	Regulatory Item
ITEM_DESC	Regulatory Item Description
FORMULA_NO	Formula Number
FORMULA_VERSION	Formula Version

Request Notifications

The workflow sends a notification to the contact person, requesting that a document be rebuilt.

The body of the Hazard Communication Outbound Information Notification for a formula or recipe validity rule change follows:

Regulatory Item: &ITEM_NO

Item Description: &ITEM_DESC

Formula No: &FORMULA_NO

Formula Version: &FORMULA_VERSION

The body of the Hazard Communication Outbound Information Notification for a regulatory item property change follows:

Regulatory Item: &ITEM_NO

Item Description: &ITEM_DESC

Partner Application Data Change Workflow

The Partner Application Data Change Workflow notifies the workflow recipient of a data change at the partner application. The workflow is instantiated by the XML Gateway.

Setting Up the Partner Application Data Change Workflow

Set up the Partner Application Data Change Workflow as follows:

1. Verify that the GR: Partner Application Site ID profile option is set up.
2. Enable the Regulatory Send Outbound Message event.
3. Enable the subscription to the event.
4. Set up AME rules for the event.

Regulatory Property Change Inbound Event

This business event is triggered by the partner application to notify the Regulatory Document Manager that the regulatory data changed at the partner application.

Event Name

oracle.apps.gr.message.send

Subscriber

Subscriber Workflow:

Regulatory Outbound Information

Oracle Approval Management Transaction Name:

Regulatory Document Manager, oracle.apps.gr.reg.documentmanager

Recommended Attributes for Approval Configuration

Parameter	Description
ORGN_ID	Organization ID
ITEM_NO	Regulatory Item
ITEM_NAME	Regulatory Item Description
PROPERTY_DETAILS	Property Details

Request Notifications

The workflow sends a notification to the contact person stating that the property data or value changed at the partner application.

The body of the Regulatory Outbound Information Notification follows:

```

Organization ID:           &ORGN_ID

Regulatory Item:          &ITEM_NO

Regulatory Description:   &ITEM_NAME

```

Property Name: &PROP_NAME

Current Property Value: &PROP_VAL

Proposed Property Value: &PROPSD_PROP_VAL

The following item attributes were sent in by the Partner Application but have no corresponding entry in Oracle Regulatory Management:

Property Name: &UNMAP_PROP_NAME

Current Property Value: &UNMAP_PROP_VAL

Proposed Property Value: &UNMAP_PROPSD_PROP_VAL

Regulatory Item Information Request Workflow

The Regulatory Item Information Request workflow notifies the workflow recipient of a regulatory item information request by the partner application. The workflow is instantiated by the partner application.

Setting Up the Regulatory Item Information Request Workflow

Set up the Regulatory Item Information Request workflow as follows:

1. Verify that the GR: Partner Application Site ID profile option is set up.
2. Enable the Regulatory Send Outbound Message event.
3. Enable the subscription to the event.
4. Set up AME rules for the event.

Regulatory Item Information Request Inbound Event

This business event is triggered by the partner application to request regulatory item information. This information is sent to the Regulatory Document Manager.

Event Name

oracle.apps.gr.message.send

Subscriber

Subscriber Workflow:

Regulatory Outbound Information

Oracle Approval Management Transaction Name:

Regulatory Document Manager, oracle.apps.gr.reg.documentmanager

Recommended Attributes for Approval Configuration

Parameter	Description
ORGN_ID	Organization ID
FROM_ITEM	From Item
TO_ITEM	To Item

Request Notifications

The workflow sends a notification to the contact person requesting regulatory item information for the requested item details. The body of the Regulatory Item Information Request Notification is as follows:

```
Regulatory Data for the range of items listed below has been requested  
by the Partner Application:
```

```
Organization:  &ORGN_ID
```

```
From Item:    &FROM_ITEM
```

```
To Item:      &TO_ITEM
```

```
Please Note: Accept will generate GR Regulatory Item Information XML  
Outbound Message. Close will close the notification and end processing.
```

Understanding OPM Hazard Communication XML Messages

XML messages are enabled through the XML Gateway. These messages allow for the passing of data between the application and an Oracle partner or customer.

The interface point for the partner application is the Oracle Transport Agent as it is used by the XML Gateway. The Oracle Transport Agent manages server validation, message encryption, and the delivery of both inbound and outbound messages.

A message sent from and received by the Oracle E-Business Suite is transported from or to the Oracle Transport Agent through Oracle Advanced Queuing as it is implemented by the XML Gateway. The message is placed into the appropriate queue directly, or it can be placed in a queue through the use of Oracle Workflow.

Oracle Workflow Business Event System

The Oracle XML Gateway uses the Oracle Workflow Business Event System to publish and subscribe to application business events and to trigger message creation or consumption.

Oracle Advanced Queuing Interface

The XML Gateway Execution Engine interfaces with Oracle Advanced Queuing to stage outbound XML messages or receive inbound XML messages for processing.

Oracle Workflow Interface

The XML Gateway Execution Engine interfaces actively with Oracle Workflow to notify the XML Gateway system administrator regarding system or process errors, or the partner contact for data errors.

Oracle Transport Agent Interface

The Oracle Transport Agent interfaces with Oracle Advanced Queuing to deliver outbound messages and to receive inbound messages. The Transport Agent server is a Java-based servlet that uses the Transport Agent Messaging Protocol to support:

- Guaranteed one-time delivery
- Message encryption
- Server-to-server certificate authentication

OPM Hazard Communication XML Messages

Following are the XML messages generated:

GR: Document Rebuild Required (Outbound) XML Message

This message is sent to the Oracle partner application when a new product is created that contains a regulatory item, or when a regulatory item in a product composition changes. It specifies which product the Oracle partner application must retrieve for safety information evaluation.

Transaction Definition

Following is the transaction definition for the XML message:

Parameter	Definition
Party Type	Exchange
Transaction Type	GR
Transaction Subtype	GRRRO

Parameter	Definition
Transaction Description	Alert the Oracle partner application that a regulatory document rebuild is required.
Standard Code	UNIVERSAL
Direction	OUT
External Transaction Type	REGDOCREBUILD
External Subtype	REQUEST
Queue	ECX_OUTBOUND

Data Definition

The data values required for this message are sent from the procedure that determines if a document rebuild is required. An XML Gateway map is created based on the following DTD:

```
<!-- grgrrrod.dtd -->
<!-- $Header: grgrrrod.dtd 115.1 2005/05/03 15:02:15 kprasad noship $ -->
<!ELEMENT DocumentRebuildRequired (Product+) >
<!-- -->
<!--Identifies the Product/Item -->
<!ELEMENT Product (ProductName,ProductIdentifier,ProductIdentifierType)
>
<!ELEMENT ProductName (#PCDATA)>
<!ELEMENT ProductIdentifier (#PCDATA)>
<!ELEMENT ProductIdentifierType (#PCDATA)>
```

GR: Regulatory Item Ordered (Outbound) XML Message

This message is sent to the Oracle partner application when a new sales order with at least one Regulatory Item is sent for Pick Release. It specifies which sales order the Oracle partner application must retrieve for regulatory information evaluation.

Transaction Definition

Following is the transaction definition for the XML message:

Parameter	Definition
Party Type	Exchange
Transaction Type	GR
Transaction Subtype	GRIOO
Transaction Description	Alerts the Oracle partner application that a regulatory item appeared on a sales order.
Standard Code	UNIVERSAL
Direction	OUT
External Transaction Type	REGITEMORDERED
External Subtype	NOTIFY
Queue	ECX_OUTBOUND

Definition

The data values required for this message are sent in the Pick Release function in Oracle Order Management. An XML Gateway map is created based on the following DTD:

```

<!-- grgriood.dtd -->
<!-- $Header: grgriood.dtd 120.1 2007/12/13 21:18:52 plowe ship $ -->
<!ELEMENT RegulatoryItemOrdered (SalesOrder*) >
<!--Identifies the Sales Order -->
<!ELEMENT SalesOrder
(Organization,Number,CustomerId,CustomerName,OrderLines*)>
<!ELEMENT Organization (#PCDATA)>
<!ELEMENT Number (#PCDATA)>
<!ELEMENT CustomerId (#PCDATA)>
<!ELEMENT CustomerName (#PCDATA)>
<!ELEMENT OrderLines
(ProductName,RecipientSiteId,ShipToAddress1,ShipToAddress2)>
<!ELEMENT ProductName (#PCDATA)>
<!ELEMENT RecipientSiteId (#PCDATA)>
<!ELEMENT ShipToAddress1 (#PCDATA)>
<!ELEMENT ShipToAddress2 (#PCDATA)>

```

GR: Document Dispatch History (Outbound) XML Message

This message is sent to the Oracle partner application when a new Document Dispatch History record is written.

Transaction Definition

Following is the transaction definition for the XML message:

Parameter	Definition
Party Type	Exchange
Transaction Type	GR
Transaction Subtype	GRDDO
Transaction Description	Alerts the Oracle partner application that a document was dispatched in the Oracle E-Business Suite.
Standard Code	UNIVERSAL
Direction	OUT
External Transaction Type	REGDISPATCHHIST
External Subtype	NOTIFY
Queue	ECX_OUTBOUND

Data Definition

The data values required for this message are sent. An XML Gateway map is created based on the following DTD:

```
<!-- grgrddod.dtd -->
<!-- $Header: grgrddod.dtd 115.3 2005/06/07 16:05:53 kprasad noship $ -->
<!ELEMENT DispatchHistory (DispatchRecord+) >
<!--Contains Dispatch Information -->
<!ELEMENT DispatchRecord ( DocumentName?, DocumentVersion?,
AssociatedItem, AssociatedCasNum?, RecipientSiteId, RecipientId,
DateSent,
DispatchMethodCode, DocumentCode?, DisclosureCode?, DocumentLanguage?,
UserId) >
```

```

<!-- -->
<!ELEMENT DocumentName (#PCDATA)>
<!ELEMENT DocumentVersion (#PCDATA)>
<!ELEMENT AssociatedItem (#PCDATA)>
<!ELEMENT AssociatedCasNum (#PCDATA)>
<!ELEMENT RecipientSiteId (#PCDATA)>
<!ELEMENT RecipientId (#PCDATA)>
<!ELEMENT DateSent (#PCDATA)>
<!ELEMENT DispatchMethodCode (#PCDATA)>
<!ELEMENT DocumentCode (#PCDATA)>
<!ELEMENT DisclosureCode (#PCDATA)>
<!ELEMENT DocumentLanguage (#PCDATA)>
<!ELEMENT UserId (#PCDATA)>

```

GR: Regulatory Item Information (Outbound) XML Message

This message is sent to the Oracle partner application after receiving a request for item information. It contains all pertinent regulatory properties for each item in the requested range.

Transaction Definition

Following is the transaction definition for the XML message:

Parameter	Definition
Party Type	Exchange
Transaction Type	GR
Transaction Subtype	GRIIO
Transaction Description	Sends regulatory item information to the Oracle partner application.
Standard Code	UNIVERSAL
Direction	OUT
External Transaction Type	REGITEMINFO
External Subtype	PROCESS

Parameter	Definition
Queue	ECX_OUTBOUND

Data Definition

The data values required for this message are sent. An XML Gateway map is created based on the following DTD:

```
<!-- $Header: grgriiod.dtd 120.0 2005/06/20 07:01:11 kprasad noship $
-->
<!ELEMENT RegulatoryItemInformation (Organization?, Product*)>
<!-- -->
<!-- -->
<!ENTITY % pressUnit "(atm | bar | in_hg | mm_hg | in_H2O | mm_H2O | psi
| psf | Pa)">
<!ENTITY % volUnit "(cc | in3 | ft3 | m3 | gl | l | ml | cy | oz | bbl |
pt | qt)">
<!ENTITY % massUnit "(lb | oz | US_ton | metric_ton | kg | gm | mg |
stone | gr | ct)">
<!ENTITY % densUnit "(g_per_l | pct | lbs_per_gl | mg_per_ml)">
<!ENTITY % tempUnit "(F | C | K | na)">
<!ENTITY % qualifier "(= | > | < | >= | <=)">
<!ENTITY % miscUnit "(air_is_1.0 | water_is_1.0 | mg_per_l_H2O | other|
pct | cP | na)">
<!ENTITY % severity "(acute | chronic | none)">
<!ENTITY % YesNo "(Yes | No | Unknown)">
<!ENTITY % stateValue "(Liquid | Gas | Solid)">
<!-- -->
<!-- -->
<!ELEMENT Organization (#PCDATA)>
<!ELEMENT Product ( ProductName, ProductDescription?, ProductIdentifier,
ProductIdentifierType, Ingredient*, RelatedItem*,
AutoIgnitionTemp1?, AutoIgnitionTemp1Qualifier?, autoIgnitionTemp1Unit?,
BoilingPoint1?, BoilingPoint1Qualifier?, boilingPoint1TemperatureUnit?,
```

BoilingPoint2?, Color?, DecompositionTemp1?,
DecompositionTemp1Qualifier?,

decompositionTemp1Unit?, EvaporationRate1?, evaporationRate1Qualifier?,

FlashPoint1?, FlashPoint1Qualifier?, flashPoint1MethodUsed?,
flashPoint1TempUnit?, FlashPoint2?,

FreezingPoint1?, FreezingPoint1Qualifier?, freezingPoint1Unit,

HazardousPolymerization?, LowerFlameLimit?, UpperFlameLimit?,
ConsumerUse?,

TradeSecretNumber?, Carcengenicity?, ImmiscibleInWater?,

MeltingPoint1?,

meltingPoint1TempUnit?, MoistureAbsorbing?, SolubilityInEthanol?,
SolubilityInFats?,

SolubilityInGlycerol?, OtherSolubility?, SolubilityInWater?,
MolecularWeight?,

Mutagenicity?, Odor?, pH1?, pH2?, SkinIrritant?, SpecificGravity1?,
VaporPressure1?,

VaporPressure1Temp?, vaporPressure1TempUnit?, VaporDensity?,
vaporDensityUnit?,

VolatileOrganicContentPercent?, VolatileWeight?, volatileVolume?,
StrongOxidizer?,

TradeSecretExpireDate?,

TradeSecretRegistration?, UNNumber?, classificationType?,
UnSubsidiaryRisk?,

TransportRegulationPackingGroup?,

EmergencyRespNumber?,

EmergencyStorageCode?, KemmlerNo?, IMDGClass?, MarinePollutant?,
ADRRIDNumber?,

ADRItemCode?, ADNRWaterway?,

HazchemCode?, ChemtrecNumber?, CANUTECCNumber?, EPARegistrationNumber?,
SupplierNumber?,

```

SupplierRevisionDate?,

SupplierDatePrepared?, ProductUse?, OtherPhysicalAndChemicalProperty*)>
<!-- -->
<!ELEMENT ProductName (#PCDATA)>
<!ELEMENT ProductIdentifier (#PCDATA)>
<!ELEMENT ProductIdentifierType (#PCDATA)>
<!ELEMENT ProductUse (#PCDATA)>
<!ELEMENT ProductDescription (#PCDATA)>
<!ELEMENT ConsumerUse (#PCDATA)>
<!ELEMENT TradeSecretNumber (#PCDATA)>
<!ELEMENT Carcengenicity (#PCDATA)>
<!ELEMENT Ingredient (Code?, Name?, Classification?,ClassificationType?,
Percent1?, Percent1Qualifier?, PercentWeightVolumeIdentifier?)>
<!ELEMENT Code (#PCDATA)>
<!ELEMENT Name (#PCDATA)>
<!ELEMENT Classification (#PCDATA)>
<!ELEMENT ClassificationType (#PCDATA)>
<!ELEMENT Percent1 (#PCDATA)>
<!ELEMENT Percent1Qualifier (#PCDATA)>
<!ELEMENT PercentWeightVolumeIdentifier (#PCDATA)>
<!ELEMENT RelatedItem (Code?, Name?)>
<!--ELEMENT Code - already defined-->
<!--ELEMENT Name - already defined-->
<!-- -->
<!-- -->
<!ELEMENT AutoIgnitionTemp1 (#PCDATA)>
<!ELEMENT AutoIgnitionTemp1Qualifier (#PCDATA)>
<!ELEMENT autoIgnitionTemp1Unit (#PCDATA)>
<!ELEMENT BoilingPoint1 (#PCDATA)>
<!ELEMENT BoilingPoint1Qualifier (#PCDATA)>
<!ELEMENT boilingPoint1TemperatureUnit (#PCDATA)>
<!ELEMENT BoilingPoint2 (#PCDATA)>
<!ELEMENT freezingPoint1Unit (#PCDATA)>
<!ELEMENT ImmiscibleInWater (#PCDATA)>
<!ELEMENT MeltingPoint1 (#PCDATA)>
<!ELEMENT meltingPoint1TempUnit (#PCDATA)>
<!ELEMENT MoistureAbsorbing (#PCDATA)>
<!ELEMENT Color (#PCDATA)>

```

```
<!ELEMENT DecompositionTemp1 (#PCDATA)>
<!ELEMENT DecompositionTemp1Qualifier (#PCDATA)>
<!ELEMENT decompositionTemp1Unit (#PCDATA)>
<!ELEMENT EvaporationRate1 (#PCDATA)>
<!ELEMENT evaporationRate1Qualifier (#PCDATA)>
<!ELEMENT LowerFlameLimit (#PCDATA)>
<!ELEMENT UpperFlameLimit (#PCDATA)>
<!ELEMENT FlashPoint1 (#PCDATA)>
<!ELEMENT FlashPoint1Qualifier (#PCDATA)>
<!ELEMENT flashPoint1MethodUsed (#PCDATA)>
<!ELEMENT flashPoint1TempUnit (#PCDATA)>
<!ELEMENT FlashPoint2 (#PCDATA)>
<!ELEMENT FreezingPoint1 (#PCDATA)>
<!ELEMENT FreezingPoint1Qualifier (#PCDATA)>
<!ELEMENT HazardousPolymerization (#PCDATA)>
<!ELEMENT MolecularWeight (#PCDATA)>
<!ELEMENT Mutagenicity (#PCDATA)>
<!ELEMENT Odor (#PCDATA)>
<!ELEMENT pH1 (#PCDATA)>
<!ELEMENT pH2 (#PCDATA)>
<!ELEMENT SkinIrritant (#PCDATA)>
<!ELEMENT SolubilityInEthanol (#PCDATA)>
<!ELEMENT SolubilityInFats (#PCDATA)>
<!ELEMENT SolubilityInGlycerol (#PCDATA)>
<!ELEMENT OtherSolubility (#PCDATA)>
<!ELEMENT SolubilityInWater (#PCDATA)>
<!ELEMENT SpecificGravity1 (#PCDATA)>
<!ELEMENT VaporPressure1 (#PCDATA)>
<!ELEMENT VaporPressure1Temp (#PCDATA)>
<!ELEMENT vaporPressure1TempUnit (#PCDATA)>
<!ELEMENT VaporDensity (#PCDATA)>
<!ELEMENT vaporDensityUnit (#PCDATA)>
<!ELEMENT VolatileOrganicContentPercent (#PCDATA)>
<!ELEMENT VolatileWeight (#PCDATA)>
<!ELEMENT volatileVolume (#PCDATA)>
<!ELEMENT StrongOxidizer (#PCDATA)>
<!ELEMENT TradeSecretExpireDate (#PCDATA)>
<!ELEMENT TradeSecretRegistration (#PCDATA)>
<!ELEMENT UNNumber (#PCDATA)>
```

```

<!ELEMENT classificationType (#PCDATA)>
<!ELEMENT UnSubsidiaryRisk (#PCDATA)>
<!ELEMENT TransportRegulationPackingGroup (#PCDATA)>
<!ELEMENT EmergencyRespNumber (#PCDATA)>
<!ELEMENT EmergencyStorageCode (#PCDATA)>
<!ELEMENT KemmlerNo (#PCDATA)>
<!ELEMENT IMDGClass (#PCDATA)>
<!ELEMENT MarinePollutant (#PCDATA)>
<!ELEMENT ADRRIDNumber (#PCDATA)>
<!ELEMENT ADRIItemCode (#PCDATA)>
<!ELEMENT ADNWaterway (#PCDATA)>
<!ELEMENT HazchemCode (#PCDATA)>
<!ELEMENT ChemtrecNumber (#PCDATA)>
<!ELEMENT CANUTECCNumber (#PCDATA)>
<!ELEMENT EPARegistrationNumber (#PCDATA)>
<!ELEMENT SupplierNumber (#PCDATA)>
<!ELEMENT SupplierRevisionDate (#PCDATA)>
<!ELEMENT SupplierDatePrepared (#PCDATA)>
<!ELEMENT OtherPhysicalAndChemicalProperty (OPCPName?, Property*)>
<!ELEMENT OPCPName (#PCDATA)>
<!ELEMENT Property (PropertyName?, PropertyValue?)>
<!ELEMENT PropertyName (#PCDATA)>
<!ELEMENT PropertyValue (#PCDATA)>

```

GR: Regulatory Item Information Request (Inbound) XML Message

This message is sent to the Oracle E-Business Suite by the Oracle partner application.

Transaction Definition

Following is the transaction definition for the XML message:

Parameter	Definition
Party Type	Exchange
Transaction Type	GR
Transaction Subtype	GRIRI
Transaction Description	Requests regulatory item information.

Parameter	Definition
Standard Code	UNIVERSAL
Direction	IN
External Transaction Type	REGITEMDATAREQ
External Subtype	PROCESS
Queue	ECX_INBOUND

Data Definition

The data values required for this message are sent using an XML Gateway map created with a Target Action for the Execute Procedure that references the Export Regulatory Item Data API name as the procedure name. Constant parameters such as the API version used in the call to the API are set using the Assign Variable Value action. Variable parameters for use in the call to the API are mapped using the following DTD:

```
<!-- grgririd.dtd -->
<!-- $Header: grgririd.dtd 115.2 2005/06/10 14:38:35 kprasad noship $ -->
<!ELEMENT RegulatoryInformationRequest (Request) >
<!ELEMENT Request (Organization?, FromItemName, ToItemName) >
<!--Identifies the range of items -->
<!ELEMENT Organization (#PCDATA)>
<!ELEMENT FromItemName (#PCDATA)>
<!ELEMENT ToItemName (#PCDATA)>
```

GR: Regulatory Property Change (Inbound) XML Message

This message is sent to the Oracle E-Business Suite by the partner application. Data contained in the message is used by the Partner Application Data Change Workflow to send a Notification to the Regulatory Document Manager to provide changes made to properties in the partner application.

Transaction Definition

Following is the transaction definition for the XML message:

Parameter	Definition
Party Type	Exchange

Parameter	Definition
Transaction Type	GR
Transaction Subtype	GRPCI
Transaction Description	Details of item property changes made in the partner application.
Standard Code	UNIVERSAL
Direction	IN
External Transaction Type	REGPROPCHANGE
External Subtype	PROCESS
Queue	ECX_INBOUND

Definition

An XML Gateway map is created based on the following DTD:

```
<!-- grgrpcid.dtd -->
<!-- $Header: grgrpcid.dtd 115.2 2005/06/10 14:38:51 kprasad noship $
-->
<!ELEMENT RegulatoryPropertyChange (Item+) >
<!--Identifies the item -->
<!ELEMENT Item (Organization?, Name, Property+) >
<!-- -->
<!ELEMENT Organization (#PCDATA)>
<!ELEMENT Name (#PCDATA)>
<!ELEMENT Property (propertyName, propertyValue)>
<!--Identifies the property -->
<!ELEMENT propertyName (#PCDATA)>
<!ELEMENT propertyValue (#PCDATA)>
```

GR: Document Dispatch (Inbound) XML Message

This message is sent to the Oracle E-Business Suite by the partner application. The data contained in the message is used as parameters to call the Document Dispatch API.

Transaction Definition

Following is the transaction definition for the XML message:

Parameter	Definition
Party Type	Exchange
Transaction Type	GR
Transaction Subtype	GRDDI
Transaction Description	Information pertaining to dispatch of a regulatory document outside the Oracle E-Business Suite.
Standard Code	UNIVERSAL
Direction	IN
External Transaction Type	REGDOCDISPATCH
External Subtype	PROCESS
Queue	ECX_INBOUND

Data Definition

The data values required for this message are sent from the database trigger on `gr_document_dispatch`. An XML Gateway map is created based on the following DTD:

```
<!-- $Header: grgrddid.dtd 115.3 2005/06/23 14:40:03 pbamb noship $ -->
<!ELEMENT DocumentDispatch (Document+) >
<!--Identifies the Document and Dispatch Information -->
<!ELEMENT Document (Name, Location, Version, Category, DocumentType,
FileFormat, FileDescription?, AssociatedItem?, AssociatedCasNum?,
RecipientSiteId, RecipientId, DateSent,
DispatchMethodCode, DocumentCode, DisclosureCode, DocumentLanguage,
UserId, OrganizationCode?) >
<!-- -->
<!ELEMENT Name (#PCDATA)>
<!ELEMENT Location (#PCDATA)>
<!ELEMENT Version (#PCDATA)>
<!ELEMENT Category (#PCDATA)>
<!ELEMENT DocumentType (#PCDATA)>
<!ELEMENT FileFormat (#PCDATA)>
<!ELEMENT FileDescription (#PCDATA)>
```

```
<!ELEMENT AssociatedItem (#PCDATA)>
<!ELEMENT AssociatedCasNum (#PCDATA)>
<!ELEMENT RecipientSiteId (#PCDATA)>
<!ELEMENT RecipientId (#PCDATA)>
<!ELEMENT DateSent (#PCDATA)>
<!ELEMENT DispatchMethodCode (#PCDATA)>
<!ELEMENT DocumentCode (#PCDATA)>
<!ELEMENT DisclosureCode (#PCDATA)>
<!ELEMENT DocumentLanguage (#PCDATA)>
<!ELEMENT UserId (#PCDATA)>
<!ELEMENT OrganizationCode (#PCDATA)>
```

Entering the Dispatch History

The Document Dispatch History window displays a list of safety documents sent with regulated items. The history includes the name of the document sent, its recipient, the date sent, and the method used to send the document.

Send a safety document as a fax, e-mail, or attached to a shipment. To record a manually dispatched safety document, enter a dispatched document on this window and save it.

You can use folders with this window.

Prerequisites

- Set up regulatory documents to dispatch.
- Set up the Human Resources application.

To enter a safety dispatch history:

1. Navigate to the **Document Dispatch History** window. The **Find Dispatch History** window displays.
2. Click **New**.
3. Enter **Item** as the regulated item. Required.
4. Enter **Recipient** as the party to whom the document was sent. Required.
5. Enter **Recipient Site Number** as the number of the party site listing for the recipient entered in the Human Resources (Process Operations) application. Required.
6. Select the **Document** name from the document catalog.

7. Enter **Date Sent** as the date that the document was dispatched.
8. Enter **Dispatch Method** as the method that was used to dispatch the document. Only the existing items are allowed in this field. Seeded dispatch methods are:
 - **Delivered with Shipping Documents** if the documents were delivered as part of the shipping document package.
 - **Email** if the documents were sent as part of an email.
 - **Fax** if the documents were sent by facsimile.
 - **Mail** if the documents were sent by the postal service.
 - **XML Gateway** if the documents were sent using the XML gateway.You can seed additional dispatch methods.
9. The following fields are display only:
 - **Document Category** is the category assigned to the document in iSignatures Files Approval. For example, MSDS for Regulatory Item is a typical document category.
 - **Document Description** is a description of the document selected.
 - **Document Version** is the version of the document selected.

To display the safety document dispatch history:

1. Navigate to the **Document Dispatch History** window. The **Find Dispatch History** window displays.
2. Enter fields as described in "Finding a Dispatch History Record."
3. Click **Find**. The window displays a history of documents that fit the search criteria entered.

To display a document attachment:

1. Select the desired row in the dispatch history.
2. Click **Open Document**. The document opens.

To display recipient information:

1. Select the desired **Recipient** row.
2. From the **Actions** menu, click **Recipient Information**.
3. The **Customers-Standard** window displays. Refer to the *Oracle Receivables User's Guide* for an explanation of this window.

Finding a Dispatch History Record

Use the Find Dispatch History window to find a specific document that was dispatched.

To find a document dispatch history:

1. Navigate to the **Find Dispatch History** window.
2. Enter any of these fields to narrow your search:
 - **Item** as the regulated item. The **Item Description** displays.
 - **CAS Number** as the Chemical Abstracts Service registry number.
 - **Ingredient** as a regulatory item with the Ingredient indicator selected.
 - **Document** as the name of the document dispatched. The **Document Description** displays.
 - **Document Category** as the category assigned to the document in iSignatures Files Approval. For example, MSDS for Regulatory Item is a typical document category.
 - **Recipient** as the individual to whom the dispatch was sent.
 - **Date Sent** as the date or date range that the documents were dispatched.
 - **Dispatch Method** as the method that was used to dispatch the document. Dispatch methods are described in "Entering the Dispatch History."
3. Click **Find**.

Running Regulatory Management Reports

This topic describes the available OPM Regulatory Management reports. Reports are available through the application's Standard Report Submission window. Refer to the *Oracle Applications User's Guide* or the online help topics for detailed information on running reports.

This chapter covers the following topics:

- Disclosure Code Details Report
- Field Name Class Codes Report
- Field Name Codes Report
- Properties Report
- Risk Phrases Report
- Safety Phrases Report
- XML Publisher Report
- Document Dispatch History Report
- Print Regulatory Documents Report
- Viewing Lookups
- Viewing Session Parameters

Disclosure Code Details Report

Use the Disclosure Code Details Report to view all the disclosure codes and their associated descriptions set up in OPM Regulatory Management.

To submit the disclosure code details report:

1. Navigate to the **Submit Request** window.

2. Enter the name of the report in the **Request Name** field.
3. Complete the other fields on the **Submit Request** window.
4. Click **Submit Request**.

Field Name Class Codes Report

Use the Field Name Class Codes Report to view the field name class codes that are set up in OPM Regulatory Management.

The report displays the field name class codes in the language range selected along with their associated descriptions.

To submit the field name class codes report:

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Select the **From Language** in the range that you want to display field name class codes for. Field name class codes display in every language in the range.
4. Select the **To Language** in the range that you want to display field name class codes for. Field name class codes display in every language in the range.
5. Click **OK**.
6. Complete the other fields on the **Submit Request** window.
7. Click **Submit Request**.

Field Name Codes Report

Use the Field Name Codes Report to view the field name codes that are set up in OPM Regulatory Management.

The report displays either the field name codes or field name class codes for the range and language range selected along with their associated descriptions.

To submit the field name codes report:

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.

3. Select the **Report Type** as Field Name Class Code or Field Name Code.
4. Select **Print Report For** by field name class code or field name code.
5. Select the **From Field Name Class** in the range that you want to display field name class codes for if you have selected to print the report by field name class.
6. Select the **To Field Name Class** in the range that you want to display field name class codes for if you have selected to print the report by field name class.
7. Select the **From Field Name** in the range that you want to display field name codes for if you have selected to print the report by field name.
8. Select the **To Field Name** in the range that you want to display field name codes for if you have selected to print the report by field name.
9. Select the **From Language** in the range that you want to display field name codes for. Field name codes display in every language in the range.
10. Select the **To Language** in the range that you want to display field name codes for. Field name codes display in every language in the range.
11. Click **OK**.
12. Complete the other fields on the **Submit Request** window.
13. Click **Submit Request**.

Properties Report

Use the Properties Report to view the properties that are set up in OPM Regulatory Management.

The report displays the property IDs with their associated type, length and precision, minimum and maximum range, language, and description.

To submit the properties report:

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Select the **From Property ID** in the range that you want to display properties for.
4. Select the **To Property ID** in the range that you want to display properties for.
5. Select the **Property Type**. Valid values are Alphanumeric, Date, Flag, Numeric and

Phrase

6. Select the **From Language** in which you want to display the Properties report.
7. Select the **To Language** in which you want to display the Properties report.
8. Click **Submit Request**.

Risk Phrases Report

Use the Risk Phrases Report to view the risk phrases that are set up in OPM Regulatory Management.

The report displays risk phrase codes with their associated languages and descriptions for the language range selected.

To submit the risk phrases report:

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Select the **From Language** in the range that you want to display risk phrase information for. Codes display in every language in the range.
4. Select the **To Language** in the range that you want to display risk phrase information for. Codes display in every language in the range.
5. Click **OK**.
6. Complete the other fields on the **Submit Request** window.
7. Click **Submit Request**.

Safety Phrases Report

Use the Safety Phrases Report to view the safety phrases that are set up in OPM Regulatory Management.

The report displays safety phrase codes with their associated languages and descriptions for the language range selected.

To submit the safety phrases report:

1. Navigate to the **Submit Request** window.

2. Enter the name of the report in the **Request Name** field.
3. Select the **From Language** in the range that you want to display safety phrase information for. Codes display in every language in the range.
4. Select the **To Language** in the range that you want to display safety phrase information for. Codes display in every language in the range.
5. Click **OK**.
6. Complete the other fields on the **Submit Request** window.
7. Click **Submit Request**.

XML Publisher Report

OPM Regulatory Management uses XML publisher to print the reports. The XML Publisher report lets you enter the printing parameters for the reports.

To enter the parameters for printing reports:

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Select the **Report Request** that you want to print. The **Template Application** of the report displays.
4. Select the **Template** of the report.
5. Select the **Template Locale** as the language in which you want to print the report.
6. Select the **Output Format** for the report.
7. Click **OK**.

Document Dispatch History Report

Use the Document Dispatch History Report to view information about the print selections that have printed successfully. The report displays the date the document was sent, the recipient, item information , CAS number, and document category.

To submit the document dispatch history report:

1. Navigate to the **Submit Request** window.

2. Enter the name of the report in the **Request Name** field.
3. Enter any of the following criteria to narrow your search:
 - **Organization** to search for documents dispatched from a specific organization.
 - **From Item** and **To Item** to specify the range of item numbers for whose dispatch history you want to print the report.
 - **From Recipient** and **To Recipient** to specify the range of the recipients to whom the documents were dispatched.
 - **From Document Category** and **To Document Category** to specify the category range of the dispatched documents. For example, if you specify the range as MSDS for a Regulatory Item to MSDS for a Shipment, then all the dispatched MSDS documents for regulatory item and shipments are listed.
 - **From Date** and **To Date** to specify a date range for which you want a report for.
 - **CAS Number** to search for the dispatch history an item using its Chemical Abstract Services number.
 - **Ingredient** to search for dispatched documents related to a hazardous ingredient.
 - **Order By** to specify the order in which you want the report to be ordered. For example, you can order the reports by date.
4. Click OK.

Print Regulatory Documents Report

Use the Print Regulatory Documents Report to send (e.g., print, e-mail, or fax) applicable copies of the partner-generated documents for distribution.

To submit the Print Regulatory Documents report:

1. Navigate to the **Submit Request** window.
2. Enter the name of the report in the **Request Name** field.
3. Enter any of the following fields to narrow the scope of your report.
 - **Organization Code** to search for regulatory documents from a specific organization.
 - **From Item** is the number of the first item to include on the report.

- **To Item** is the number of the last item to include on the report.
 - Select the **From Language** in the range that you want to display regulatory documents for the items.
 - Select the **To Language** in the range that you want to display regulatory documents for the items.
 - **Document Category** as the category assigned to the document in iSignatures Files Approval.
 - **Recipient Site** as the number of the party site listing for the recipient entered in the Human Resources application.
4. Click **Submit Request**.

Viewing Lookups

Use the Process Manufacturing Regulatory Management Lookups window to maintain lookups. Each lookup has a code and a meaning. For example, lookup type YES_NO has a code Y with meaning Yes, and a code N with a meaning No. Refer to the *Oracle Process Manufacturing Systems User's Guide* for a detailed description of this window.

Viewing Session Parameters

Use the Session Parameters window to view the current system information. Refer to the *Oracle Process Manufacturing Systems User's Guide* for a detailed description of this window.

Navigation Paths

This topic explains typical navigation paths in OPM Regulatory Management.

This appendix covers the following topics:

- Navigation Paths

Navigation Paths

Although your System Administrator may have customized your navigator, typical navigation paths are described in the following table. In some cases, there is more than one way to navigate to a form. This table provides the most typical default path.

Navigation Paths

Window	Path
Additional Item Information	Regulatory Document Management:Items:Regulatory Information:Find Regulatory Items:Regulatory Item Detail:Additional Item Information
Configuration Variables	ERES Administrator:Setup:Configuration Variables
Disclosure Codes	Regulatory Document Management:Setup:Disclosure Codes
Disclosure Codes Report	Regulatory Document Management:Reports:Run
eRecord Generator	ERES Administrator:Utilities:eRecord Generator

Window	Path
Evidence Store - Administrator	ERES Administrator:Inquiry:Evidence Store
Evidence Store - User	ERES User:Inquiry:Evidence Store
Exploded Components	Regulatory Document Management:Items:Regulatory Information:Find Regulatory Items:Regulatory Item Detail:Exploded Components
Field Name Class Assignments	Regulatory Document Management:Field Names:Field Name Class Assignments
Field Name Class Codes Report	Regulatory Document Management:Reports:Run
Field Name Class Responsibilities	Regulatory Document Management:Setup:Field Names:Field Name Classes:Responsibilities
Field Name Classes	Regulatory Document Management:Setup:Field Names:Field Name Classes
Field Name Codes Report	Regulatory Document Management:Reports:Run
Field Names	Regulatory Document Management:Setup:Field Names:Field Names
Files Approval	iSign Administrator:Files Approval iSign User:Files Approval
Find Regulatory Items	Regulatory Document Management:Items:Regulatory Information
Hazard Classifications	Regulatory Document Management:Setup:Hazard Classification Codes
Item Group Codes	Regulatory Document Management:Setup:Item Group Codes
Item Group Codes Report	Regulatory Document Management:Reports:Run
Item Relationships	Regulatory Document Management:Items:Item Relationships:Find Item Relationships:Find

Window	Path
Master Item Associations	Regulatory Document Management:Items:Master Item Associations
Organization Items	Regulatory Document Management:Items:Find Organization Items:Find
Physical Data	Regulatory Document Management:Items:Regulatory Information:Find Regulatory Items:Regulatory Item Detail:Physical Data
Print Regulatory Documents Report	Regulatory Document Management:Reports:Run
Process Manufacturing Regulatory Management Lookups	Regulatory Document Management:Other:Lookups
Product Class Codes Report	Regulatory Document Management:Reports:Run
Profile Options	Regulatory Document Management:Other:Profile Options
Properties	Regulatory Document Management:Setup:Field Names:Properties
Properties Report	Regulatory Document Management:Reports:Run
Regulatory Information	Regulatory Document Management:Items:Regulatory Information:Find Regulatory Items:Regulatory Item Detail
Risk Phrases	Regulatory Document Management:Setup:Risk Phrases
Risk Phrases Report	Regulatory Document Management:Reports:Run
Safety Phrases	Regulatory Document Management:Setup:Safety Phrases
Safety Phrases Report	Regulatory Document Management:Reports:Run
Security Rules	ERES Administrator:Setup:Security Rules

Window	Path
Session Parameters	Regulatory Document Management:Other:Session Parameters
XML Elements	ERES Administrator:Setup:XML Elements
XML Generator	ERES Administrator:Utilities:XML Generator
XML Report Publisher	Regulatory Document Management:Reports:Run

Regulatory Management APIs

This appendix covers the following topics:

- Regulatory Management APIs
- Introducing the Regulatory Management APIs
- Regulatory Management API Support Policy
- Technical Requirements
- Technical Overview
- Basic Business Needs
- Input Data Sources
- Stored Procedure
- Standard Parameters
- Value-ID Conversion
- Dispatch History API

Regulatory Management APIs

This topic describes the parameters needed for the API, as well as the table structure and the associated details. The topics discussed are:

- Introducing the Regulatory Management APIs
- Basic Business Needs
- Standard Parameters
- Dispatch History API

Introducing the Regulatory Management APIs

The Regulatory Management APIs let you import information from another system into the OPM Regulatory Management tables. When you import this information you can include all pertinent information using a tool that does not have cryptic IDs and system specific information. The interface ensures that your imported data contain the same detail as those you enter manually on the OPM Regulatory Management windows.

Regulatory Management APIs are written in PL/SQL that can be called by your own programs. To make use of these APIs, code your wrapper function that passes the appropriate parameters to the APIs. Your program is responsible for connecting to a database before calling an API function, and disconnecting from the database upon return. You can choose to write log files before calling and after returning from a function. If there is a problem during execution of a call, then the APIs return one of the following status codes:

- S for success
- E for error
- U for unknown or unexpected status
- N for item requiring a location
- V for inventory shortage exists
- I for incomplete manual transactions exist
- G for over allocation exists

Regulatory Management API Support Policy

Regulatory Management APIs are supported by Oracle. This means:

- Oracle provides objects and libraries needed to use the APIs and the documentation for their use.
- Oracle ensures that the APIs function as designed.
- Oracle does not support customer generated programs that use the APIs.

Technical Requirements

Regulatory Management APIs make use of the following standard Oracle Applications packages:

- FND_API - the standard Oracle Applications API version checking function. This is used by the stored procedure to check for a valid API version number and also contains constant variables such as TRUE and FALSE.
- FND_MESSAGE - the standard Oracle Applications messaging function. This is used by the stored procedure to report status and error handling.
- FND_PUB_MSG - the standard Oracle Applications message retrieval function used to search the procedure messages.

These packages are installed as part of the current release. Refer to the *Oracle Applications Coding Standards* manual for additional details.

Technical Overview

Regulatory Document Management APIs are designed to operate in an OPM 11i environment only. They offer the following basic API functionality:

- Creating, updating, and deleting information.
- Proper encapsulation.
- Synchronous processing following the business hierarchy.
- Detailed and translatable error messages.

Basic Business Needs

These APIs let you feed information from a third party vendor into OPM Regulatory Management.

Following are some of the important characteristics for these APIs:

Code Reuse

You can maximize code reuse from all application development tools, including PL/SQL, Oracle Forms, and Oracle Reports.

Ease of Integration

You can integrate APIs into other applications and enabling technology, such as Oracle Workflow Server, Oracle Internet Commerce & Oracle WebSystem, and Oracle EDI Gateway.

Insulation from Changes

You can encapsulate the structure of schema to prevent changing schema structures from affecting other applications.

Consistent Behavior

You can hide Object logic specific to an application from other applications, and to ensure that this logic is correctly invoked by other applications and customers.

Robust Validation

You can validate all incoming information into Oracle Applications.

Input Data Sources

Flat File

Input data to the user wrapper function comes from a flat file source. This is processed by the wrapper and header information, passed as parameters, to the stored procedure in a synchronous mode. However, along with the standard parameters, the header information is passed as a PL/SQL table. In this mode, the calling function monitors the success or failure (return code) from the called procedure. It also provides an option to COMMIT work done by the procedure.

Batch File

Input data to the user wrapper function comes from a batch file. This is processed by the wrapper and header information passed, as parameters, to the stored procedure in an asynchronous mode. In this mode, the calling function does not monitor the success or failure of each individual record. The Oracle Message FND_PUB_MSG functionality is used to audit the calls.

Online User Interface (UI)

Input data to the user wrapper function comes from a window or another user interface. This is processed by the UI and the details passed, as parameters, to the stored procedure in a synchronous mode. In this mode, the UI calling function monitors the success or failure (return code) from the called procedure. It also provides an option to COMMIT work done by the procedure.

Stored Procedure

The stored procedure is called with the appropriate parameters forwarded in a PL/SQL table format. The procedure validates each record from this table and then processes the appropriate functional logic as required. The procedure writes appropriate messages to the Oracle Messages table. These are informational as determined by the logic. These can be interrogated by the calling wrapper function through the GET MESSAGES functionality.

The stored procedure calls other validation procedures in the course of its execution; a modular approach has been adopted. Functions called by these procedures do not use IN/OUT parameters as these have been removed from the Oracle 8 coding standards.

On successful completion of the procedure, a success unit is in place that can be optionally COMMITTED. The decision as to whether a COMMIT is issued on successful completion is under the control of the calling code and deliberately outside the scope of the API procedures.

Standard Parameters

API standard parameters are a collection of parameters that are common to most APIs. The following paragraphs explain the standard parameters that are used in APIs and their interpretation.

Some of the standard parameters apply to all APIs regardless of the nature of the business function they perform. For example, `p_api_version` and `x_return_status` are included in all APIs.

However, some parameters are applicable for certain types of APIs and not applicable for other types. For example, `p_commit` is applicable for APIs that change the database state, and not applicable for read APIs.

Standard parameters are included in all APIs whenever applicable.

Standard IN parameters:

- `p_api_version`
- `p_init_msg_list`
- `p_commit`
- `p_validation_level`

Standard OUT parameters:

- `x_return_status`
- `x_msg_count`
- `x_msg_data`

Parameter	Type	IN/OUT	Required	Validation
p_api_version	varchar2	IN	Y	Validates version compatibility. The version sent by the calling function is compared to the internal version of the API and an unexpected error (U) is generated if these do not match.
p_init_msg_list	varchar2	IN	N	Used to specify whether the message list can be initialized on entry to the API. It is an optional parameter, and if not supplied, then it defaults to FND_API.G_FALSE, and the API does not initialize the message list.
p_commit	varchar2	IN	N	Used to specify whether the API can commit its work before returning to the calling function. If not supplied, then it defaults to FND_API.G_FALSE.

Parameter	Type	IN/OUT	Required	Validation
x_return_status	varchar2	OUT	-	Specifies whether the API was successful or failed. Valid values are S - successful, E - failed due to expected error, U - failed due to unexpected error.
x_msg_count	number	OUT	-	Specifies number of messages added to message list.
x_msg_data	varchar2	OUT	-	Returns the messages in an encoded format. These messages can then be processed by the standard message functions as defined in Business Object API Coding Standards document.

Value-ID Conversion

IDs are usually used to represent primary and foreign entity keys, and for internal processing of attributes. They are not meaningful and are hidden. Besides IDs, attributes have values that represent them. Those values are meaningful and are used for display purposes. In general, APIs operate only on IDs.

For example, an item is represented by an ID, the number column `item_id`. This ID is its primary key and is used for all internal processing of the item. Besides this ID, an item

is represented by a value, the varchar2 column item_no. This value is displayed when you choose an item. Therefore, an item can be identified by either its ID or value, in this case item_no.

The following set of rules are for the conversion process:

- Either ID or value, or both can be passed to an API. But, when both values are passed, ID based parameters take precedence over value based parameters. For example, if both parameters are passed, the value based parameter is ignored and the ID based parameter is used.
- When both the value and ID of an attribute are passed to an API, a message informs the API caller that some of the input has been ignored.
- This message is not an error message. The API continues with its regular processing.
- Each value has to resolve into one ID. Failure to resolve a value into an ID is an error and is associated with an error message. The API aborts processing and returns with a return status of error.

Dispatch History API

The Dispatch History API stores details about the distribution of Regulatory documents. If the document has not already been stored in the fnd_documents table, then the eSignatures file upload API does. The API is called from within the Oracle E-Business Suite or by other sources, such as third party applications.

Following is the definition of the Dispatch History API:

Parameter	Required	In/Out	Description
p_item	N	IN	The item or product that the document is related to.
p_cas_number	N	IN	CAS number of the item or product that the document is related to.
p_recipient_id	Y	IN	Document recipient ID.
p_recipient_site_id	Y	IN	Document recipient site ID.

Parameter	Required	In/Out	Description
p_date_sent	Y	IN	Date document was sent to recipient.
p_dispatch_method_code	Y	IN	Method used to send the document to recipient.
p_document_id	N	IN	If the document is already in the system, then this is the ID of the document. Otherwise, the Files Upload API is called to upload the file.
p_document_location	N	IN	Physical location of the document. Required if the document is not currently in the system.
p_document_name	N	IN	Actual name of the file. Required if the document is not currently in the system.
p_document_version	N	IN	Document version. Required if the document is not currently in the system.
p_document_category	N	IN	Category to assign document to. Required if the document is not currently in the system.

Parameter	Required	In/Out	Description
p_file_format	N	IN	Format of the file. For example, XML, PDF. Required if the document is not currently in the system.
p_file_description	N	IN	Description of document. Required if the document is not currently in the system.
p_document_code	Y	IN	Type of regulatory document. For example, US16, CA16. Required if the document is not currently in the system.
p_disclosure_code	N	IN	Disclosure code used to generate the document. Required if the document is not currently in the system.
p_language	N	IN	Language that document was generated in. Required if the document is not currently in the system.
p_organization_code	N	IN	Organization the document was created for.
p_user_id	Y	IN	User ID used in Standard Who columns.

Parameter	Required	In/Out	Description
p_creation_source	N	IN	Specifies the application calling this API. Valid values are 0 - External application, 1- Internal application, 2 - Form. Required if the document is not currently in the system.

Glossary

ACGIH

American Conference of Governmental Industrial Hygienists. US organization that establishes occupational exposure limits for substances.

Action Phrase

Action phrases replace conflicting phrases with the same phrase type and hierarchy. For example, the phrases "Wash with soap and water" and "Do not wash with soap under any circumstances" can be replaced with a conflict action phrase such as "Rinse with water" that prints on documents when the conflict occurs.

ADN

European regulations for the international transport of dangerous goods via inland waterways in the European states.

ADR

European regulations for the international transport of dangerous goods via road in the European states.

ANSI

American National Standards Institute.

Auto Ignition Point

The temperature that a substance spontaneously ignites at.

Boiling Range/Point

The temperature or range of temperatures that a liquid turns to vapor at.

Carcinogen

A substance that causes cancer.

CAS

Chemical Abstracts Service. Catalogs chemical substances.

CAS Registry Number (CASRN, RN)

The Chemical Abstracts Service numbers assigned to items. A unique accession number assigned by the Chemical Abstracts Service, a division of the American Chemical Society. Other than being guaranteed unique to a given compound, this number has no particular meaning. A CAS Registry Number includes up to 9 digits that are separated into 3 groups by hyphens. The first part of the number, starting from the left, has up to 6 digits; the second part has 2 digits. The final part consists of a single check digit.

CEPA

Canadian Environmental Protection Act. A Canadian environmental law that requires the domestic substances list (DSL) and the non-domestic substances list (NDSL).

CERCLA

Comprehensive Environmental Response, Compensation, and Liability Act. A US EPA law.

CHEMTREC

Chemical Transportation Emergency Center. Provides 24-hour transportation emergency information to registered companies.

CONEG

Conference of North Eastern Governors. Passed laws in several states that regulate the amount of lead, mercury, cadmium, and hexavalent chromium in packaging materials.

Corrosive

A substance that changes or destroys living tissue.

COSHH

Control of Substances Hazardous to Health. UK legislation.

Dangerous Preparation Directive (1999/45/EC)

A preparation is classed as dangerous and is therefore subject to the provisions of Directive 1999/45/EC if it:

- Contains at least one dangerous substance within the meaning of Article 2 (definitions of dangerous substances).
- Is considered to be dangerous, after evaluation, because of its physicochemical properties, or the dangers that it poses to health or to the environment. The methods of evaluation for these three criteria are specified in the annexes of the directive.
- Is not considered dangerous within the strict meaning of the Directive but may

nevertheless present a specific danger. These preparations are specified in the annex to the Directive.

Dangerous Substance Directive (67/548/EEC)

The Dangerous Substance Directive (67/548/EEC) was introduced in 1967. It lists common provisions on the classification of dangerous substances. This includes the placement of a substance into one or several defined classes of danger characterized the type and severity of the adverse effects that the substance can cause. The directive also advises the packaging of dangerous substances, because adequate packaging protects from the known dangers of a substance. Labeling of dangerous substances is provided, because the label on the packaging informs about the nature of the dangers of the substance inside and appropriate safety measures to apply during handling and use.

Density

The mass per unit volume of a material.

Disclosure Code

Disclosure codes are groupings of legislative reporting levels linked to legislative or recipient requirements and their respective recipients.

DOT

Department of Transportation. A US government agency that regulates the transportation of hazardous materials.

DSL

Domestic Substances List. A Canadian list of items manufactured in or imported to Canada. The DSL is regulated by the CEPA.

E-records

Electronic Records.

EEC

European Economic Community.

EH40

In UK COSHH regulations, Guidance Note EH40 lists occupational exposure limits for substances in air.

EHSC

Environment, Health, and Safety Committee.

EINECS

European Inventory of Existing Chemical Substances. An EEC list of known chemical substances tracked by EINECS and CAS numbers.

EINECS Number

The number assigned to the items on the EINECS list.

ELINCS

European List of Notified Chemical Substances. Supplements the EINECS list.

ELINCS Number

The number assigned to the items in the ELINCS list.

EPA

Environmental Protection Agency. A US government agency that regulates and enforces environmental laws.

ERG Number

Emergency Response Guidebook Number. The item reference number in the ERG.

Explosive

A substance that releases pressure, gas, and heat suddenly when subjected to certain conditions.

Explosive Limit

The concentration range in percent of a gas or vapor that can explode.

Exposure Authority

Exposure authorities are companies or legislative bodies that determine the item exposure limit reporting requirements.

Exposure Type

Exposure types are the kinds of exposures that must be reported such as long-term, short-term, minimum, and maximum.

Flammable

A substance that produces a flame when subjected to certain conditions.

Flash Point

The minimum temperature that a liquid is ignitable at.

Freezing Point

The temperature that a liquid begins to form crystals or solidify at.

Hazard

The dangerous properties of a substance.

Hazard Classification

Hazard classifications are required when shipping chemicals within Europe and when other countries ship products to Europe. For example, an item that causes severe burns to humans and kills aquatic life if disposed of in rivers would have the European hazard classifications of Very Corrosive and Dangerous to the Environment.

Hazard Groups

Hazard groups describe the types of dangers that European hazard classifications have. For example, an item with the European hazard classifications of Very Corrosive and Dangerous to the Environment is included in the Health-Toxic and Environmental hazard classification groups.

HMIS

Hazardous Material Information System. A US system of rating the health, flammability, and reactivity of substance hazards for workers. Substances in each hazard category are rated from 0-4.

IARC

International Agency for Research on Cancer. The IARC ranks actual and potential carcinogens.

IATA Class

International Air Transport Association classification.

ICAO

International Civil Aviation Organization.

IMDG Class

International Maritime Dangerous Goods classification.

Irritant

A substance that inflames living tissue, but does not irreversibly change or destroy it.

Item Groups

Item groups group items that are in the same chemical family or share the same properties such as organic acids. You can consolidate similar ingredients in a product

into one item group on a document.

Kemmler Code

A European hazard identification number that is required on vehicles transporting dangerous goods in Europe.

LC50

Lethal Concentration Fifty. The calculated concentration of a substance in air that kills 50% of the test group with a single exposure.

LCLO

Lethal Concentration Low. The lowest concentration of a substance in air that has caused death in humans or animals (except LC50.) The reported concentrations can be entered for periods of exposure less than (acute) or greater than (sub-acute and chronic) 24 hours.

LD50

Lethal Dose Fifty. The calculated amount of a substance that kills 50% of the test group with a single dose.

LDLO

Lethal Dose Low. The lowest dose of a substance introduced by a route other than inhalation, over a period of time, in one or more portions, that has caused death in humans or animals (except LD50).

LTEL

Long-term exposure limit.

MEL

Maximum exposure limit.

Melting Point

The temperature that a solid begins to liquefy at.

MFAG Table Number

The Medical First Aid Guide reference numbers for items.

MITI Number

Japanese Ministry of International Trade and Industry number for the item.

MSDS

Material Safety Data Sheets are documents that provide information about hazardous

materials. OSHA regulation 29 CFR Part 1910.2000, European Directive 91/155/EEC, and Canadian Regulations exist for MSDS documents.

Mutagen

A substance that alters the genetic makeup of a cell.

NDSL

Non-domestic Substances List. Lists items that are not part of the Canadian market and are considered non-domestic. The list is based on TSCA.

Neoplastigen

A substance that causes benign or malignant growths.

NFPA

National Fire Prevention Association. Promotes fire protection and prevention.

NPRI List

National Pollution Regulatory Initiative. The NPRI list provides Canadian Regulatory legislation.

Odor Threshold

The lowest concentration of a substance detectable by smell.

Occupational Safety and Health Administration Hazard Communication Standard (HCS), Subpart Z, Toxic and Hazardous Substances (29 CFR 1910.1200)

In order to ensure chemical safety in the workplace, information must be available about the identities and hazards of the chemicals. The OSHA HCS, Subpart Z, Toxic and Hazardous Substances (29 CFR 1910.1200), requires the development and dissemination of information. Chemical manufacturers and importers are required to:

- Evaluate the hazards of the chemicals they produce or import.
- Prepare labels and material safety data sheets (MSDSs) to convey the hazard information to their downstream customers.

Employers with hazardous chemicals in their workplaces must have labels and MSDSs for their exposed workers, and they must train workers to handle toxic and hazardous appropriately.

Oxidizer

A substance that causes combustion in other materials.

Partition Coefficient

The distribution of a substance or mixture between two phases, such as between a

liquid and a gas.

PEL

Permissible Exposure Limit. A workplace concentration exposure limit.

pH

The concentration of hydrogen in a solution. The number, ranging from 0 - 14 describes the degree of acidity (0 - 7) or alkalinity (7 - 14) of the solution.

Phrase Code

Phrase codes hold information about a product's dangers and qualities. For example, "Wash with Soap and Water."

PIN Number

Product Identification Number. A Canadian identification number that typically uses UN or NA numbers.

Polymerization

A chemical reaction that causes molecules to bond and form larger molecules. Polymerization is dangerous when the reaction releases large amounts of energy.

Product Class

Product classes are groupings of products with similar requirements or properties. For example, Liquids.

Property ID

Property IDs identify the different properties that are assigned to a label. For example, the boiling point label is associated with a temperature property ID. In addition, properties are set up on the Properties window and displayed on the window associated with each label on the Regulatory Information navigator.

Property Type

Property types identify the kinds of a property assigned to a label. For example, a property ID such as temperature can have a type of flag, numeric, alphanumeric, date, or phrase.

Property Value

Property values identify the valid values assigned to properties assigned the type flag. For example, the temperature property ID can have a list of valid temperature values such as Celsius, Fahrenheit, and Kelvin. The actual temperature is entered on the Regulatory Information navigator, on the property window associated with label.

Proposition 65

The Safe Drinking Water and Toxic Enforcement Act of 1986. Proposition 65 regulates warning requirements on materials that the US state of California has designated to be known carcinogens and/or teratogens.

RID

European regulations for the international transport of dangerous goods via rail in the European states.

Right-to-Know Act

A law requiring companies to supply product composition information on labels or documents or both. This law is also known as SARA Title III and is administered by the Environmental Protection Agency.

Right-to-Know Labels

The Right-to-Know Act requires companies to disclose the contents of materials by labeling containers with the ingredients.

Risk

A risk is the possibility that a substance's hazardous properties could cause harm to people or the environment.

Risk Phrase

Risk phrases supply information about the hazards of a chemical during normal use. Both European hazard classifications and risk phrases are required by EEC directives for chemical transport in Europe.

Safety Data Sheet Directive (91/155/EEC)

Provides an outline of information to be included on an MSDS for Europe.

Safety Phrase

Safety phrases supply advice on safety precautions that are appropriate when using the substance.

SARA

Superfund Amendments and Reauthorization Act of 1986. SARA is a US regulation concerning emergency response plans and the Right-to-Know Act. SARA is administered by the Environmental Protection Agency.

SARA 313

The SARA 313 Reportables List is a yearly report of emissions to the air, land, and water of materials designated by SARA Title III, Section 313. Statements about these materials

must be reported on MSDSs.

STEL

Short-term Exposure Limit. The maximum concentration of a material that you can be exposed for 15 minutes.

TCLo

Toxic Concentration Low. The lowest concentration of a material in air that humans or animals have been exposed for any given period of time, that has produced any toxic effect in humans, or produced a carcinogenic, neoplastigenic, or teratogenic effect in animals or humans.

TDG Act

Transportation of Dangerous Goods Act. Canadian legislation.

TDL_o

Toxic Dose Low. The lowest dose of a material introduced by any route, other than inhalation, over any given period of time, and reported to produce any toxic effect in humans or to produce carcinogenic, neoplastigenic, or teratogenic effects in animals or humans.

Teratogen

A substance that causes birth defects.

TLV

Threshold Limit Value. The maximum concentration of a material that a worker can be exposed to during an eight hour day.

TLV-C

Ceiling Threshold Limit Value. The maximum concentration of a material that a worker can be exposed to under any conditions.

Toxic

A substance that has a particular lethal dose.

Toxic Dose

The amount time and concentration of a substance that you can be exposed to under specific conditions.

Toxic Effects

Toxic effects are the known hazardous effects of a chemical substance, such as allergic or carcinogenic effects.

TSCA

Toxic Substances Control Act. A US law regulated by the Environmental Protection Agency (EPA) to control risks to human health and the environment. The EPA issues a list of substances called the TSCA Inventory.

UN Number

United Nations number. Assigned to hazardous materials to identify them during shipping and transportation.

Vapor Density

The relative weight of a vapor compared to air.

Vapor Pressure

The pressure a vapor exerts above its own liquid in a closed vessel.

Workplace Hazardous Material Information System

The Workplace Hazardous Materials Information System is Canada's hazard communication standard. The key elements of the system are cautionary labeling of containers of WHMIS "controlled products", the provision of material safety data sheets (MSDSs), and worker education programs.

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