



U.S. FDA TITLE 21 CFR PART 11 COMPLIANCE ASSESSMENT OF SAP® RECIPE MANAGEMENT

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SUMMARY

Based upon SAP AG's interpretation of the U.S. FDA Title 21 Code of Federal Regulations Part 11 (21 CFR Part 11) rule and the functions and features discussed within this document, SAP AG believes that the recipe management software in the SAP® ERP application fully complies with 21 CFR Part 11.



U.S. FOOD AND DRUG ADMINISTRATION (FDA) TITLE 21 CFR PART 11 ASSESSMENT

Recipe Management

Recipe management functionality in the SAP Product Lifecycle Management (SAP PLM) application enables you to manage product and process development in the process industry from the first idea to implementation in manufacturing and integration in the supply chain. The application bundles the sophisticated recipe management functionalities of SAP PLM into a separate, complete solution that is also found in the SAP ERP application. With this recipe management software you can monitor and control the entire range of activities needed to create products from research and development to production. And you can track and share detailed recipe information about process definitions, formulas, raw materials, and finished products – across departments, company facilities, and corporate boundaries – to ensure accuracy and increase speed.

The basis for the following investigation is the recipe management software in SAP ERP 2005.

Security

The recipe management software discussed here – including the SAP Recipe Management application – is built on top of the SAP NetWeaver® platform. Therefore, all security features of the SAP NetWeaver Application Server component are valid for the recipe management software. For details, please refer to the document called *21 CFR Part 11 Compliance Assessment of SAP NetWeaver®*.

E-Records

FDA Requirement

The FDA requires that computer systems at life sciences companies allow for the logging and tracking of changes on business objects and dependent objects in a software environment that complies with FDA regulations. Computer systems must provide functionality to log changes, as well as creation and deletion applied to business objects and to dependent objects (for example, configuration data). The minimal necessary information the system has to provide is as follows:

- Old value of an attribute of the changed business object
- New value of this attribute
- Person who changed the value
- Date and time of change (SAP Recipe Management uses application server time)
- Action (create, modify, or delete)

Change, Status, Authorization Management, and Versioning in SAP Recipe Management

Recipes and Formulas

Change Management for Recipes and Formulas

SAP Recipe Management supports various processing methods allowing different levels of freedom during recipe and formula editing and guaranteeing change documentation to varying degrees. Depending on the recipe type, the processing method can either be freely chosen or is firmly defined. Using engineering change management functionality, you can create and manage different change statuses for the same object.

Change Management for Recipes

Recipe editing is regulated not only by the processing method, but also by status management. You can use the recipe status, for example, to release recipes and protect them against improper changes.

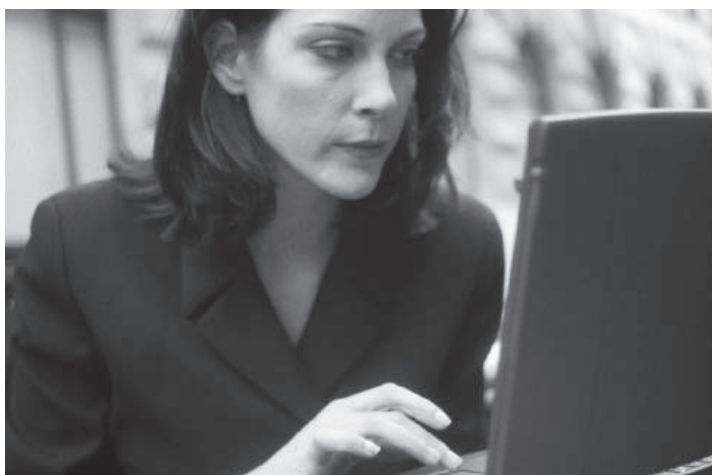
Depending on the recipe type, status management can be active or inactive. It can take dependencies between change statuses into account, and you can enhance it using your own status profile. In this way, your process will become more or less strictly regulated depending on how you decide to combine processing methods and status management.

The required combination of processing method and status management has to be activated for recipe types. For compliance with the requirements of Good Manufacturing Practices (GMPs) we strongly recommend that you do the following:

- Activate status management for your recipe types
- Specify that change master records be used

Recipe editing software with change master records enables specially authorized users to plan, create, and document change statuses in a detailed manner. Changes you make are logged in change documents as well. In addition, you obtain a change history in the form of defined change statuses.

The function for evaluating the use of change master records lets you evaluate which change master records are used in recipes and formulas as well as their scopes of application. You receive an overview of the change statuses and scopes of application created using a particular change master record.



The function for evaluating change documents lets you evaluate the change documents created for a recipe or change status. You receive information about the values that were changed, the person who changed them, and the date on which they were changed.

Change Management for Formulas

In addition to the processing method, formula editing is also regulated by the scopes of application of a formula and their statuses. Via the status, you release a formula, for example, and protect released formulas against improper changes.

Depending on the type of formula assignment in the recipe, you can freely choose the processing method for independent formulas. Their scopes of application and change statuses may deviate from those of the recipe to which they are assigned. With dependent formulas, the recipe determines the processing method, change statuses, and statuses of the formula (see the documentation of the individual processing methods).

For compliance with requirements of GMPs, we recommend you assign dependent formulas to your recipe types and make the use of change master records obligatory. You can make these settings in customizing software for *Recipe Management* in the IMG activity *Recipe Settings*.

The function for formula editing with change master records enables specially authorized users to plan, create, and document changes in a detailed manner. You obtain a change history in the form of defined change statuses.

The function for evaluating the use of change master records is used to evaluate how change master records are used in recipes and formulas and their scopes of application. You obtain an overview of the change statuses and scopes of application created using a particular change master record.

Scopes of Application and Statuses

In recipe management software, you can use the following types of status:

- System statuses are defined in standard SAP software. You use them to document the processing stages defined for a formula in standard SAP software.
- User statuses are part of a status profile that you defined and can use to add to the system statuses if necessary. User statuses enable you to map enterprise-specific processes into standard SAP software.

Using scopes of application, you restrict the usage of formulas and recipes to certain regional and organizational units. Every scope of application has its own status. Using statuses, you release the relevant object within the scope of application and protect it against improper changes.

If required, you can also generally release recipes, that is, without restricting the scope of application. You can add your own user statuses to the status network of formulas and recipes.

Scope of Application and Status Management for Recipes

Change statuses of recipes go through different stages during their processing, and each stage permits different processing steps and business transactions. Change statuses of recipes are, for example, created, used, and then replaced by new change statuses. Their application areas can be unrestricted or limited to a certain regional or organizational unit.

With status management and the scope of application functionality, SAP software also allows you to ensure that the sequence of processing stages laid down for the recipe is observed and documented.

System statuses document the processing stages of a change state for a recipe defined in standard SAP software. They are set or deleted according to a fixed status network when you carry out certain steps or processes in the recipe. At the same time, a status set in the recipe determines which recipe data may be changed and which processes may be carried out. System statuses, therefore, ensure that the sequence of processes defined in the standard software is observed.

The recipe status network guarantees the correct sequence of processing stages within a change state. In addition, it checks the preceding and succeeding change state when a status is changed. This check applies to all status changes that influence the changeability of recipe data. The check ensures that the processing sequence is observed across all change states of a recipe.

User statuses belong to one of the status profiles that you define and add to the recipe system statuses defined in standard SAP software. The status profile applied to the change states of a recipe depends on the recipe type.

User statuses map enterprise-specific processes into the SAP software. They document transactions that are not logged in the standard software and ensure that certain transactions not defined in standard SAP software are executed.



You can use the scope of application to restrict the usage of change states for a recipe to certain regional or organizational units. You do this by entering a separate validity period along with a status for each scope of application entry. You need to do so in these situations:

- If you want to release a change state for a restricted usage only
- If you want to release a change state for different usages with different validity periods

You use the status of a scope of application to document which processing status the recipe has with regard to the usage defined in the scope of application. In this way, you decide separately for each scope of application entry whether and when you want to release the relevant change state of the recipe.

Scope of Application and Status Management for Formulas

You use the scope of application to define the following:

- What use (combination of rating and regional or organizational unit) the data records are specified for, for objects without direct usage. You specify a validity period with the appropriate status for each scope of application entry. In this way you can guarantee that the data records are released separately for each usage.
- What active direct use a particular status is valid for, for objects with their own direct usage. The scope of application entry is useful if the usage of the scope of application entry applies to the active direct usage of the data record. Only then does the scope of application entry define the status of the data record.

In the formula you can use the status to do the following:

- Prohibit changes (for example, the status *Released*) or to warn about changes (for example, the status *For Release*).
- Prohibit output on reports (for example, the status *In Process*)

Authorization Concept

Using the authorization objects of recipe management, you can protect recipe and formula data, statuses, and scopes of application against unauthorized access and changes (see the customizing area for *Recipe Management* under *Set Up Authorizations*).

Versioning

You can use this function to create versions and drafts of an object and replace objects with other objects. When you do so, the software keeps a record of all the relationships between the drafts and versions, as well as between the replacement and replaced objects. This enables you to keep track of your product development and production and quickly find the objects you have used. At present, versioning is only supported for recipes.

Trials

There is no predefined change management concept available yet for recipe trials. Nevertheless, changes can be tracked using the electronics records tool in SAP ERP. This tool enables you to change logging settings easily, without the need for technical modifications, and to carry out an FDA-compliant evaluation of the changed data. The software enables you to do the following:

- Activate and deactivate logging for the required data elements, tables, and long texts specifically, and without the need for technical modifications.
- Determine for each object – in the case of corrections or a system update – whether you want to retain the logging settings that currently exist in the software or make different logging settings for the newly imported data.
- Use the evaluation function to find and display the changed objects according to certain criteria, and therefore carry out a GMP-compliant evaluation of the changed data.

Digital Signature

In case digital signature is needed within SAP Recipe Management in SAP ERP 2005, the encapsulated signature tool in SAP NetWeaver Application Server can be implemented on a project basis. Here are some of the particulars:

- The software must consist entirely of coding from the ABAP™ programming language – which is the case for SAP Recipe Management – as a prerequisite for using the encapsulated signature tool. The prerequisite does not apply to user interfaces; the tool can also be utilized with user interfaces programmed in a language other than ABAP, such as JAVA. In this case, security and authentication issues have to be considered carefully to avoid security gaps.
- You must have SAP NetWeaver Application Server 6.20 or higher to use the encapsulated signature tool.

For further information refer to the implementation guide titled *Digital Signature-Tool* (SAP note 700495).



Compliance of SAP Recipe Management with 21 CFR Part 11

The following table summarizes how SAP Recipe Management complies with each requirement of 21 CFR Part 11.

Part 11 Clause	Assessment of SAP® Recipe Management
11.10(a)	The SAP® Recipe Management application provides complete audit trails for recipes, formulas, and trials within the application. The audit trail records are secured from unauthorized access.
11.10(b)	All electronic records generated in SAP Recipe Management are accurate, complete, and presented in a human-readable format. Electronic records in SAP Recipe Management can be printed or exported into several industry-standard formats such as Adobe PDF and Microsoft Excel.
11.10(c)	All electronic records can be maintained in the active database or archived to accommodate all required retention periods even when software is upgraded. Access to these records is secured by authorization profiles.
11.10(d)	Robust security administration and authorization profiles assure system access. Changes to security profiles are recorded in the SAP NetWeaver® Application Server component.
11.10(e)	SAP Recipe Management provides complete audit trails for recipes, formulas, and trials within the application. Change documents can be written and engineering change management functionality can be used to track changes. For trials the electronic records tool in the SAP ERP application can be used. The audit trail records are secured from unauthorized access.
11.10(f)	The software allows you to control the processing statuses of objects in SAP Recipe Management using status management and scope of application functionality. In this way you can enforce the proper sequence of operations as required by the applicable regulation. SAP Recipe Management provides control only over product development processes, not manufacturing processes such as the one referenced (batch). You can control manufacturing processes by using enterprise resource planning (ERP) components such as production planning software for process industries.
11.10(g)	SAP NetWeaver Application Server executes authority checks in conjunction with its robust security administration and authorization profiles to ensure only authorized individuals can access the system, electronically sign a record, and access or perform the operation at hand. SAP NetWeaver Application Server also records changes to authorization profiles.
11.10(h)	N/A

Part 11 Clause	Assessment of SAP Recipe Management
11.10(i)	The product innovation life cycle (PIL) for SAP software development requires that all personnel responsible for developing and maintaining SAP offerings have the education, training, and experience to perform their assigned tasks. A wide range of additional education and training offerings and regular assessments of individual training requirements ensure a process of continuous learning for SAP staff involved in the development and support of all SAP software.
11.10(j)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of the computer system.
11.10(k)	N/A
11.30	For open systems, SAP NetWeaver Application Server supports interfaces with complementary software partners that supply cryptographic methods such as public key infrastructure (PKI) technology.
11.50(a)	The encapsulated signature tool can be implemented to satisfy these requirements.
11.50(b)	The encapsulated signature tool can be implemented to satisfy these requirements.
11.70	The encapsulated signature tool can be implemented to satisfy these requirements.
11.100(a)	The encapsulated signature tool can be implemented to satisfy these requirements.
11.100(b)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of the computer system.
11.100(c)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of the computer system.
11.200(a)(1)	SAP NetWeaver Application Server requires two distinct components – a user ID and a password – to perform each and every electronic signature. By design, SAP NetWeaver Application Server does not support continuous sessions where only a single component is necessary subsequent to the first signing.
11.200(a)(2)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of the computer system.
11.200(a)(3)	SAP NetWeaver Application Server user and security administration functions ensure that the attempted use of an individual's electronic signature by someone other than the genuine owner requires the collaboration of two or more individuals.
11.200(b)	SAP NetWeaver Application Server provides a certified interface to biometric devices such as fingerprint- and retinal-scanning devices. Look for SAP partners that handle security in the SAP Service Marketplace extranet.
11.300(a)	SAP NetWeaver Application Server user and security administration functions provide the necessary controls to ensure that no two individuals have the same combination of identification code (user ID) and password.

11.300(b)	SAP NetWeaver Application Server can be configured to force users to change passwords at various intervals. It provides system checks to prevent users from repeating passwords or using combinations of alphanumeric characters that are included in user IDs. User IDs can also be invalidated, for example, when an employee leaves the company.
11.300(c)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of the computer system.
11.300(d)	SAP NetWeaver Application Server fulfills this requirement and behaves as demanded by the requirement.
11.300(e)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of the computer system.

REFERENCES

For more information, look up the following references, many of which are found in the SAP Service Marketplace extranet (authorization required):

- help.sap.com: *SAP NetWeaver '04 Security Guide*
- help.sap.com: *SAP NetWeaver 2004s Security Guide*
- help.sap.com: *SAP NetWeaver Application Server ABAP Security Guide*
- SAP brochure: *21 CFR Part 11 Compliance Assessment of SAP NetWeaver '04/SAP NetWeaver Application Server 2004s*
- SAP white paper: *Complying with U.S. FDA Title 21 CFR Part 11 for the Life Sciences Industry*
- SAP white paper: *SAP NetWeaver: Providing the Building Blocks for Effective Governance, Risk, and Compliance Management*
- Implementation guide titled *Digital Signature Tool* (attached in SAP note 700495)
- FDA Title 21 CFR Part 11 Electronic Records; Electronic Signatures: Final Rule, March 1997
- help.sap.com: Recipe Management
- help.sap.com: Engineering Change Management
- help.sap.com: Production Planning for Process Industry (PP-PI)
- help.sap.com: Electronic Records

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