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Food Contact Materials Compliance Database

- Risk assessment and management tool -

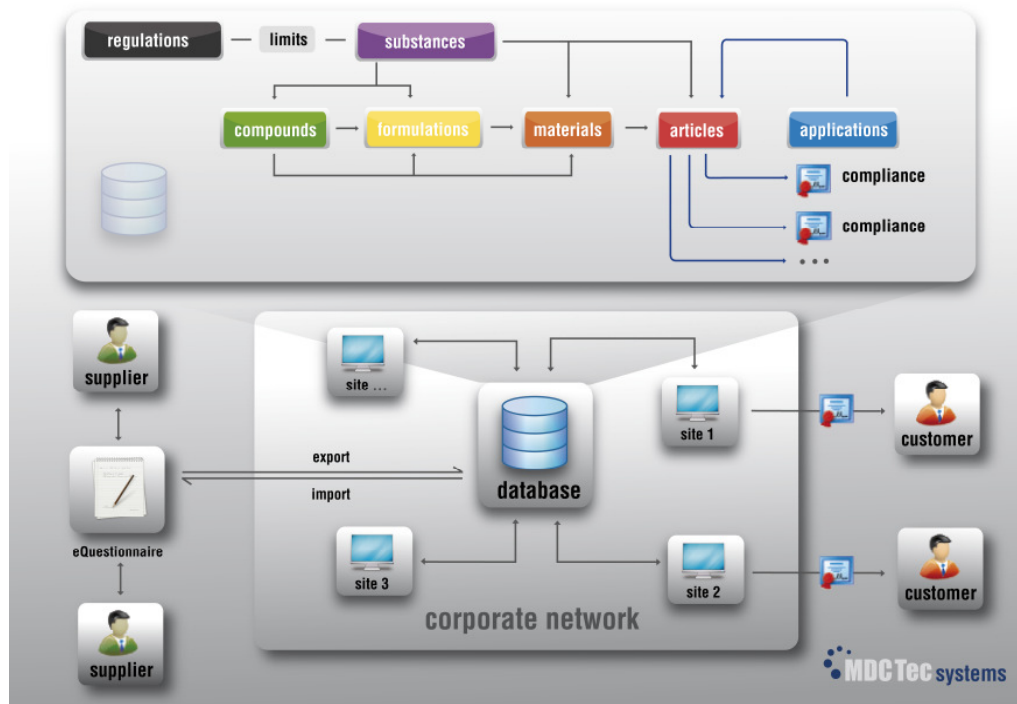
MDCTec's new compliance concept for food contact materials (FCM) runs under the trade mark **FCM - CoD™**, i.e. Food Contact Materials - Compliance Database ! **FCM - CoD™** enables companies and professionals to organize and carry out all FCM technology and compliance related activities starting from raw material information down to compliance certificates.

FCM - CoD™ represents a risk assessment and knowledge management environment based on modern database technology linked with professional tools, high end functionalities and user friendly interface.

The **FCM - CoD™** contains all business related regulatory, material/article and food/application related information and links them ready to use for compliance or technical purpose. Professional tools like the **FCM Chem™**, **FCM Builder™**, **FCM Oracle™** and **FCM Migration Center™** are directly linked to the **FCM - CoD™**. Through **FCM Spec™** and **FCM Comply™** specifications and compliance certificates are issued on demand.

High end functionalities, i.e. actions for applicable regulations, applicable migration limits, detailed composition, technical specifications, available migration data, related documentation and dynamic document generation are one click away.

The concept for the **FCM - CoD™** environment intends to be as flexible as possible to fulfil the needs of multinational enterprises as well as SME's. It is a combination of database technology and software tools developed with different partners, each with the highest degree of expertise in his field.



The software tools linked to the database implement functionality's beyond simple queries, i.e. results of a query from the database are inputs for the software tools. The **FCM - CoD™** environment transforms through the linked software tools information from the database into compliance certificates and specifications.

The **FCM Builder™** environment enables the users to build their own materials or articles (FCM) from raw materials in the database by tracking recipes, structures as well as full mass balance on components and impurities. It fully support all relevant information, e.g. technology, regulation, etc. and integrates any reports, technical documents and supporting documentation. On the other hand the intended applications with all relevant requirements are implemented and linked to the FCM.

The **FCM Oracle™** reports the regulatory requirements (so far EU/FDA/BfR) at any stage of the production, i.e. compounds, formulations, materials or final article. If the application for the final article and available migration data are implemented and the regulatory requirements specified and agreed with the customer, compliance of the final article is evaluated. Through the dynamic PDF function the printout of a compliance certificate and other supporting documents is possible.

The **FCM Spec™** reports the relevant technological properties at any stage of the production, i.e. compounds, formulations, materials or final article. Based on the structure of the FCM and its technological properties worst case and/or critical FCM are identified. If the application for the final article is implemented and the technological requirements agreed with the customer, the compliance with the specification is evaluated. Through the Dynamic PDF function the printout of the specification is possible.

The **FCM eQ™** is an electronic questionnaire linked to the main database facilitating the communication of compliance related information between customers and suppliers along the value chain.

The **FCM - CoD™** environment gives you the freedom of choice to make use of consultancy and testing services from any competent supplier. An offline link of the **FCM - CoD™** environment to the enterprise resource planning (ERP) system of the individual legal entities can be established by a customer specific data exchange module. Split out of legal entities because of changes in the corporate structure is no problem.

Access to the information from the database is limited to the confidentiality level attributed to individual information. Information can be shared between all sites implementing the **FCM - CoD™**. Using the **FCM Builder™**, i.e. building your own materials or articles (FCM) from raw materials in the database and implementing application as well as available migration data, generates user specific data, protected through a role based access system.

Compliance with specific migration limits is based on compositional information from the database and mass balance considerations (total transfer) or migration estimation by modelling (set-off, storage & aging, migration, etc.) as well as experimental data from laboratory testing. For safety reasons the experimental control of worst case or critical structures under worst case conditions is recommended based on worst case migration screening tests.

FCM - CoD™ screenshot - final article

The screenshot displays the FCM - CoD™ software interface for a final article. The interface is organized into several sections:

- Navigation:** Article, liding, View
- Left Sidebar:** Compound, Formulation, Product, Article, Application, Medium, Company
- Main Content Area:**
 - General:** Tradename (liding), Company (unknown), SAP, Article Name, Date, View all data
 - Tech. Data:** Area Weight (g/cm²), Thickness (µm), Sealing Temperature (°C), Density (g/cm³)
 - Documents:** Safety datasheet (checked), Technical datasheet (unchecked), Regulatory datasheet (unchecked)
 - Substances:** Table with columns: Chemical Name, %
 - Products:** Table with columns: Layer, Tradename, Group, Thickness [µm]

Layer	Tradename	Group	Thickness [µm]
1	Printing ink		3
2	Primer		1
3	Aluminum		37
4	Heatseal lacquer		6
 - Regulatory:** CFR 175.300 US
 - Migration Data:** liding, sterilisation (with a red X icon)
- Right Sidebar:**
 - Actions:** Create Compliance, Regulatory, Add Application, Add Migration Data, Find Similar Articles, Edit, Delete, Copy Article, New Article
 - Global Actions:** Search, Find similar articles, Find Substance, Find SML, Find Regulatory

FCM - CoD™ screenshot - regulatory requirements:

The screenshot displays the 'Regulatory' section of the FCM - CoD™ interface. The main content area shows a hierarchical tree view of regulatory requirements for various substances. The substances listed include:

- Printing ink**
 - ADIPIC ACID, BIS(2-ETHYLHEXYL) ESTER | 00103-23-1
 - LIMITS: SML
 - Directive 2002/72/EC: 18
 - WALSRÖDER NITROCELLULOSE E330 30%IPA
 - isopropyl alcohol | 67-63-0
 - 2-PROPANOL | 00067-63-0
 - LIMITS: SML
 - Directive 2002/72/EC: QM
 - WALSRÖDER NITROCELLULOSE E 330 | 9004-70-0
 - NITROCELLULOSE | 09004-70-0
 - LIMITS: SML
 - Directive 2002/72/EC: QM
 - 2-PROPANOL | 00067-63-0
 - LIMITS: SML
 - Directive 2002/72/EC: QM
 - Primer**
 - METHACRYLIC ACID, METHYL ESTER | 00080-62-6
 - LIMITS: SML
 - Directive 2005/79/EC: 6
 - GROUPLIMITS: SML
 - Directive 2002/72/EC: 6
 - ACRYLIC ACID, n-BUTYL ESTER | 00141-32-2
 - LIMITS: SML
 - Directive 2005/79/EC: 6
 - GROUPLIMITS: SML
 - Directive 2002/72/EC: 6
 - Aluminum**
 - Heatseal lacquer**
 - Poly(vinyl chloride) Copolymer |
 - VINYL CHLORIDE | 00075-01-4
 - LIMITS: SML
 - Directive 2002/72/EC: QM
 - Directive 78/142/EEC: 1
 - Directive 80/766/EEC: QMA
 - Polyacrylate**
 - ACRYLIC ACID, n-BUTYL ESTER | 00141-32-2
 - LIMITS: SML
 - Directive 2005/79/EC: 6
 - GROUPLIMITS: SML
 - Directive 2002/72/EC: 6

The right sidebar contains several utility sections:

 - Actions:** Show All, Hide All
 - Global Actions:** Search, Find similar articles, Find Substance, Find SML, Find Regulatory
 - Login:** You are logged in as admin, Logout

Continuous update, maintenance and support of the **FCM - CoD™** environment will be provided by **MDCTec**.

Implementation of the **FCM - CoD™** environment is not a trivial task reason for which a preliminary consultation to define your requirements is strongly recommended. Because the **FCM - CoD™** environment is under continuous development, an early link of **MDCTec's** activities with user specific interests is of common interest.

Our Vision
Compliance on Demand !