

FOOD CONTACT INFORMATION MANAGEMENT WITH FOCOS®

FOCOS® (Food Contact Software), the innovative software developed by Viaware B.V., is becoming an essential tool for packaging manufacturers and users. This software tool manages information about chemical substances contained in packaging materials, their raw materials, and all its related legislation. Viaware's director and senior consultant Kris Callaert talks about its advantages. Alessandra Lacaita reports.

Promoting FOCOS*, Viaware was the result of a joint venture between two companies with more than 20 years of experience: the Netherlands-based Clear IT Consulting and the Belgian company Techniplast Projects. These specialise respectively in customised IT development on the IBM platform with an expertise in workflow and document flow, and plastics consulting with expertise in materials, processing and legislation.

"FOCOS" is a secure web based tool that allows the user to access his data and documents from remote locations," Kris Callaert explains. "With FOCOS" you

can manage compositional information of raw materials, create and communicate customised DoCs (documents of compliance), perform calculations and manage supporting documents. It provides a structure that helps users to understand food contact legislation and to fulfill their legal obligations."

Rolling out FOCOS

In order to promote FOCOS*, Viaware organises free workshops and training sessions, presentations at fairs and conferences, trade shows and demonstrations based on actual company data.





The development of FOCOS® started in January 2013 and was based on a draft version of the Union guidance document on information within the supply chain that was published later on in December. According to Mr Callaert, "It was clear that the publication of this guidance document would have major implications in the way companies perform their compliance assessment and communication today."

During a period from May to October, a selected number of key accounts participated in a pilot of FOCOS® before being officially introduced to the market at Kunststoffen 2013 in Veldhoven, a plastics fair for the Benelux region. In October 2013 the first companies started to use FOCOS® and at the beginning of 2014 its European expansion started with workshops in Barcelona and a Cooperation agreement in Portugal.

"We want to expand sales and use of FOCOS® throughout Europe, through agents and associations," Kris Callaert says. "Besides the existing cooperations in Spain and Portugal, we now have our first contacts in Germany, Italy, Switzerland and France."

Food contact legislation

Food safety is one of the key areas within consumer protection in Europe. Food contact materials, like packaging, are often composed of a variety of materials, including plastics, inks and coatings, which are regulated on European level or on national level. A large number of small and medium size companies operating in this market are not always fully aware of all the complex legal obligations related with the products they produce or import.

Food contact legislation regulates materials and articles according to any chemical substances they contain that have the potential to migrate to the food. These chemical substances need to be evaluated and their migration must be assessed by screening, including worst-case calculations and modelling, or migration testing. A packaging producer must prove that only authorised substances of suitable quality are used and that their packaging material complies with all legal limits under the foreseen conditions of use. Before the products enter the market, a declaration of compliance or DoC must be issued, based on the actual composition of the product, in a fixed legal format.

"Management of information on these chemical substances is the first step in food contact compliance," Mr Callaert points out. "But knowing the identity of the chemicals

and their limits is only a part of the information. Information like compliance confirmation on substances from suppliers and maximum concentrations is essential to managing compliance costs. Without concentrations of substances it is impossible to perform worst-case calculations or migration modelling, as an alternative for expensive migration tests. The physical properties of these substances, including boiling point and molecular mass, will be important information in the future since they will be used for compliance assessment according to the draft technical guidance on migration testing."

Guidance documents

A recent study carried out in Ireland showed that less than five per cent of all declarations of compliance of plastic packaging materials contained all nine points legally required by the EU Regulation 10/2011. From this five per cent it is also known that more than 90 per cent is incomplete: information on substances with limitations and dual use additives is often missing and compliance with limitations is often not assessed. According to Mr Callaert, this was the sign for authorities and industry in Europe that urgent action was mandatory. Different technical working groups started preparing guidance documents for four major parts of EU Regulation 10/2011: general information on the Plastics Regulation itself, exchange of information in the supply chain, migration testing and migration modeling.

According to the EU Regulation 10/2011, the DoC of packaging materials should contain information about applicable legislation, substances with limitations and their compliance status, dual use additives, substances behind a functional barrier and conditions of use under which the producer has proven compliance of the packaging material.

Exchange of information on chemical substances is essential throughout the entire supply chain, starting with the substance producers. For this reason the guidance document on information defines the content of the DoCs for all stages of the supply chain. This provides a solid base for communication in the supply chain and improves the quality of the information exchange.

"The publication of this guidance document in December has already led to an improved information exchange and lots of new data that needs to be managed by the \triangleright

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packaging producer. Now we see companies struggling to handle the data, leading to a demand for IT tools to structurally manage it," Mr Callaert comments. "In addition, the management of changes such as those in reportable substances in raw materials is an important feature of FOCOS*. The compliance status of these reported changes needs to be re-evaluated by the packaging producer. DoCs need to be updated and actively communicated to inform the packaging user about these changes."

He continues: "Also packaging users, whose responsibility it is to select and use only compliant packaging materials for their application, use these guidance documents. This will lead to a better understanding of food contact legislation by food packers and food producers and a better understanding of the risks related to incomplete documentation.

Non-compliance might lead to excessive migration of chemical substances from the packaging materials to the food, thus creating a safety issue. Brand damage or costly recall actions are just a few of the risks the food producer is facing when using non-compliant packaging materials."

Meeting the market's requirements

Mr Callaert enumerates some of the features of FOCOS*: "It can be used within all parts of the supply chain, from chemical substance supplier up to the packaging user. FOCOS* offers the user a complete insight into the formulation of his packaging materials on the level of the chemical substances used."

"For raw materials, the software can calculate maximum use levels, the concentration of metal ions restricted by Annex 2, based on the concentrations of their salts and maximum concentrations of substances based on worst-case scenarios.

The software recalculates the concentration of substances from raw materials, over the product's formulation to concentrations in the product. Total mass transfer (100 per cent migration) can be calculated and compared with the limits from individual substances or groups of substances," Mr Callaert states. "These calculations can be done for both monolayer and multilayer materials including corrections for concentrations for substances behind a functional barrier."

In addition, these calculations can also be performed for substances that are regulated by national legislation, like BfR recommendations, Dutch Warenwet or Swiss ordinance.

FOCOS® supports the use of raw materials from different supply sources – the so-called 'generic raw materials' – allowing the creation of a worst-case variant, including the identification of substances with variations as explained by the guidance document.

Compliance motivation can be registered for every substance, using the results of calculations, modelling or migration test reports or by referring to compliance information from suppliers.





Communications with suppliers and supporting documents are managed at raw material level and dynamic overviews are generated on pending requests and expired documents. All supporting documents such as calculations, migration reports, compliance motivations and DoCs of raw materials are available at product level. A FOCOS® user always has a complete overview at hand for quality assurance auditors, customer audits or authorities.

Once the compliance work is finished, FOCOS* generates DoCs with a single mouse click for all assigned customers, based on customised templates according to the guidelines. These DoCs are than sent to customers to comply with the communication obligations. The communication of DoCs can be carried out for individual products or a combination of components.

FOCOS® supports the 'family approach' principle, where DoCs for multiple products can be created based on the compliance work of one worst-case product.

Finally, and perhaps most decisively, FOCOS® is a dynamic platform on which changes can be managed in a simple and efficient way.

With the features mentioned above, users will be able to save costs and reduce the risk of non-compliance.

Conclusion

As Mr Callaert concludes, "FOCOS" is continuously innovating and improving. Every month we have a new release of our software with new features and updates. Feedback and ideas from our customers are taken into consideration and will be used for future development. Some of the topics that we are working on today are multi-language, an API for communication with ERP and CRM systems, and integration of features from the draft technical guidance on migration testing.

"Viaware offers FOCOS" as a SaaS (Software as a Service) solution. Payment is on a monthly basis and includes maintenance, hardware, security and standard back-up. No initial investments in hardware or IT are required. All data concerning food contact is safely stored, and can only be accessed by authorised users from any location by a secure connection. On request, FOCOS" can even be installed on a customer's premises.

"Viaware also offers food contact services such as in-company training or a FO-COS* implementation service pack to ensure the fast and easy implementation of the software. Viaware can even take over the complete compliance work.

"We are confident that FOCOS* will contribute to improving food safety by providing a tool that facilitates compliance assessment and thereby reduces the compliance cost," Mr Callaert concludes. "Since we are all consumers, food safety must be a priority for all of us."

Visit: www.focos.eu

FOOD CONTACT SOFTWARE

A tool to support food contact compliance work within the plastics supply chain

Data management

Communication

Supply Chain Raw materials

Plastics Worst case calculation

Food contact Change management

Timesaver Supporting documents
Products

Compliance work

Up-to-date Cloud

Software Doc Legislation

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