

Infos du mois

THE IMPLEMENTATION OF MODELLING TOOLS TO PREDICT THE MIGRATION OF MATERIALS SUBSTANCES TO FOODSTUFF

A European legislation hard to apply

European Union is committed for several years into a standardisation process of regulatory requirements about materials in contact with food. Those requirements aim at guaranteeing the health security to avoid the contamination of food by substances issued from the packaging.

This current standardisation also aims at allowing the free movement of goods. Consequently, the European law is based on a channels approach and prescribes requirements according to the materials group. Even if the final objective is to minimize the food contamination, in practise, taking partially into account the contaminants of the whole provision chain often assesses the compliance.

In principle, European law is clear: a material « must not present a risk for human health » (art 3 of regulation CE n°1935/2004). This principle is practicable to the 17 materials groups described in the regulation. However, the implementation proves to be more complex for the operators, because of the lack of specific measures of application for 13 of the 17 materials groups. For some of these materials, there are already nationwide laws. Nevertheless, the regulatory texts concerned are sometimes old and don't take into consideration evolution of technologies and user modes as regards food contact materials. Moreover, even for covered materials, part of the compliance demonstration relies on an risks assessment, made by the operators: it is the case for substances that can be found into plastic materials, whose a certain number aren't included into the positive list (dyestuff, solvents, substances from ink, glue and adhesives and neoformed substances).

An expensive and complex packaging health security assessment

The means and strategies usually used for assessing the packaging health security intended for food contact have limits that don't allow bringing to an end the demonstration of compliance. Thus, only a few methods of specific migration measurements have been standardized and development costs in laboratories of new methods are really high. Most of the time, analyses are made on the basis of the rules fixed by the regulation from standardized conditions, which don't reflect real conditions of use. Finally, controls are executed at the end of the chains, that's why they don't take into account all the contamination risks. (for instance, the “set off” type transfer effects).

Modelling tools to answer this issue

From that review, INRA has launched research whom it has associated LNE and other partners within the « Safe Food Pack Design» program so as to develop new approaches and new tools to better demonstrate the health security of the food contact packaging. This works have already allowed to make two modelling tools at the disposal of market operators:

- SFPP3 « Safe Food Packaging Portal » version 3 available on the INRA website
- FMECA engine (developed as part of the "Safe Food Pack Design" Project)

This modelling tools SFPP3 is based on the phenomena that occur during the contamination of food by materials (diffusion of the substances in the packaging, sharing of these substances between the material and

the food). It allows to predict the contamination of a foodstuff by a chemical substance. The features of the packaging, the transfer proprieties of the substance and the conditions of use of the package take part of the calculation of the starting data:

- The packaging contact area with food
- The substance concentration into the materials
- The volume of matter and its density
- The volume and the density of the foodstuff
- The substance diffusion ratio into the materials and into the food at a given temperature.
- The substance sharing ratio between the material and the food.
- The duration and the temperature of contact between the materials and the food.

The exit data takes the form of a curve showing the kinetic of migration (substance concentration in the food according to the duration of contact), and the form of a concentration profile of the substance according to the material thickness after a chosen duration of food contact. Thanks to these results, a food contamination can be predicted at the sell-by date in the packaging. The migration values obtained shall be compared to the threshold of regulation admitted (LMS in mg/kg of food).

SFPP3 is open source. It has been developed as a way in EU to demonstrate the compliance of food contact packaging (regulation EU n°10/2011 about plastic materials). Authorities in charge of the market control recognize this method but it does not replace the analysis method of the migration. Actually, the first completes the second, adding the calculation power of a parameterizable tool, used in lack of analytic method, for proving the compliance. On the contrary, the obtained values of migration do not enable to conclude that the materials are not compliant of the materials. Actually, these values overestimate the food contamination (first hypotheses of calculation are based on the worst possible case and so maximize the migrations).

To be able to better assess the food health security in a process approach, the "Safe Food Packaging Design" research program has developed another calculation tool. This one relies on the use of an analytic method of the dangers and risks named AMDEC (Analyse des Modes de Défaillance, de leurs Effets et de leur Criticité) or also FMECA (Failure Mode Effects and Critically Analysis). This method, created in the 40s by the US army, came back in the 60s, used by NASA for the Apollo program under the name of HACCP (Hazard Analysis and critical Control Points) to be applied to the food suppliers.

The tool, called FMECAengine, which is currently under development, makes calculations based on real cases of packaged food. It aims at analysing a failure (a substance's migration) on the basis of a severity level (the migration level standardized from threshold concerning the substances toxicology) in order to establishing a critic level according to different parameters like the nature of the packaging components, the chemical substances contained in the materials, the stuff geometry and the process steps.

Three kinds of practical applications are already used as part of the research program :

- The severity assessment of an industrial step. The aim is to organise the risks concerning the whole practices and use conditions of the materials, the industrial storage of the packaging components until the preparation of the packaged food by the customers.
- The comparison of different packaging designs: it's about introducing additional constraints such as "using proprieties" in the packaging design process; The products health security is then built taking into account other packaging features like mechanic proprieties or gas permeability.
- The contamination assessment of the food by substances that can be potentially found in the packaging: from scenarios related to real cases of packaged food, a statistical distribution of overvalued diffusion ratio is

calculated in order to assess the contamination.

The goal of the FMECAengine is to better meet the requirements of the regulation CE n° 2023/2006 related to the market operators, but also to set up good practices and master the packaged food contamination risk.

From tests to modelling: LNE offers a global solution

AS a partner of the "Safe Food Pack design" project, LNE already suggests to its customers the use of modelling as a way to demonstrate the compliance of food packaging. This offer falls within a more global approach, which enables the LNE to cover needs of its customers from this following services:

- Tests of compliance upgrade for food contact materials, especially services of tests about global migration and specific migration, related to specific components (Bisphenol A, phthalates, phenolic antioxidants...);
- Regulated analyses and materials features and performances analyses, in order to demonstrate the compliance of their food contact material and obtain required proves;
- An aid and a support in RDfor the design of safer food contact packaging;
- Formations, technical regulatory support or even regulatory and scientific monitoring to help them to identify regulatory texts applicable to their food contact materials, to understand the regulatory requirements or their interpretations.

For further information, contact us at 01 30 69 10 00 or info@lne.fr

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