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Direction de la santé

Conclusions of the workshops on the conference food contact materials: Working together for safety and innovation in Europe

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The food contact material (FCM) industry is important and economically significant for the food sector and for the EU economy.

In general, many stakeholders including industry and Member States are dissatisfied with the current EU legislation which consists of a framework regulation[1], a limited number of specific rules and mutual recognition of national rules where EU specific rules have not been adopted.

There was overall agreement that a greater degree of harmonisation of the rules on the FCM sector was desirable at EU level, although there is currently no clear way forward on how to achieve this.
There was consensus that the approach chosen for plastic materials[2], i.e. individual toxicological evaluation of all substances used, cannot be rolled out on all groups of food contact materials. This would be too time consuming and resource intensive. Moreover, such an approach would not produce harmonised rules on composite materials and articles made of several materials.

Better use of the mutual recognition principle[3] was presented as a potential tool to improve the current situation. To this end it needs to be better implemented in practice.
Today many FCMs manufactured or used legally in one MS are often assessed against national rules in another MS. The national rules frequently employ different approaches for risk assessment, for analytical methodology and require specific national certification of compliance.

[1] Commission Regulation (EC) No 1935/2004 of 27 October 2004 on materials and articles intended to come in contact with food fixes general requirements for the safety of FCM

[2] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food

[3] The mutual recognition principle guarantees free movement of goods within the EU without the need to harmonisation of MS national legislation. Goods that are lawfully produced in one MS cannot be banned from sale on its territory by another MS, even if they are produced to specifications different from those applied to its own products.

To create trust and make mutual recognition a key element in the proper functioning of the EU market, more standardisation of requirements is needed at analytical, scientific and administrative level.

Such harmonisation should be integrated into the FCM framework regulation.

Participants however also cautioned that mutual recognition may only play a small part of the solution.

Risk analysis

Participants agreed that risk assessment methodologies should be harmonised. It was stressed that EFSA should drive such harmonisation and should integrate MS risk assessment capacities for all materials, taking into account exposure to substances from all FCMs and avoiding the need to undertake reassessments for the same substance in different FCMs.

The risk assessment methodologies could increasingly capitalise on modelling to predict the presence and migration of non-intentionally added substances (NIAS), to consider substance structure and/or functional groups and to employ the toxicological threshold of concern (TTC) methodology.
Information available from a range of sources should be considered (e.g. International Standard Organisation, Council of Europe).

It was suggested that functional barriers can be a useful tool to avoid risk assessment for all substances.

The importance of technical guidance on testing FCMs was highlighted. Methodologies should be available, pragmatic and provide a benefit for stakeholders, including authorities and industry.

Official controls

Efficient official controls mainly rely on targeted inspections of manufacturers and importers. It is important to streamline official control in the field of FCM with other official control of the food-chain. For example, all relevant business operators such as manufacturers and importers of FCM should be registered with the control authorities.

To promote trust and a better collaboration, inspections should follow a similar method in all MS. The BTSF framework could improve the current situation and foster the functioning of the single market in FCMs.

Inspections can be supplemented by the testing of samples but not be replaced by them. Given the many potential substances there is a lack of testing methods and references.

For official controls, declarations of compliance (DoC) are important documents. They are however only mandatory at EU level if a specific EU legislation for FCMs has been adopted (like in the case of plastic).
Some MS (e.g. DK) require such DoC for all FCMs as it is a very useful tool for both official controls and food industry.

Yet, in practice the quality of declarations, if provided, is quite variable. This creates difficulties for trade in the single market. It would thus be a first step to improve the current situation if models for DoC could be provided for those FCMs for which no specific measures exist at EU level.

Industry should consider it part of due diligence to produce DoC with the necessary details to allow their clients to use products with confidence. Control authorities and industry should thus collaborate in the creation of such DoC models.

A general legal obligation for industry to produce a DoC for all FCM could facilitate the free movement of FCM and facilitate official controls.

Challenges and Innovation opportunities

Industry representatives recalled that it is society which is the driver of innovation, requiring more functional, less expensive or more environmentally friendly solutions.

Furthermore it was stated that decisions on authorisation of materials are often based on more aspects than scientific assessments of health concerns. However, authorisation decisions did not consider the trade-off effect of limiting innovation of products. Some substances were also prohibited without considering the impact of using alternatives.
The outcome of risk assessments was not sufficiently predictable. One problem was the misuse of the precautionary principle.

Industry is also of the opinion that authorisation in the EU takes too long in comparison to other economic regions of the world. Furthermore small and medium sized businesses have difficulties to determine compliance of their products given the complex nature of the legal obligations.

For industry, harmonised rules at EU-level were clearly preferable. It was stated that divergent MS rules and risk assessments would hinder rather than foster the functioning of the internal market.