## **Implementation of the Food Contact Materials Regulation (EC) No 1935/2004**

2015/2259(INI) - 18/07/2016 - Committee report tabled for plenary, single reading

The Committee on the Environment, Public Health and Food Safety adopted the own-initiative report by Christel SCHALDEMOSE (S&D, DK) on the implementation of the Food Contact Materials (FCMs) Regulation ((EC) No 1935/2004.

Members acknowledged that the <u>Framework Regulation (EC) No 1935/2004</u> constitutes a solid legal basis, the objectives of which remain relevant. They considered that the adoption of **specific measures** to overcome shortcomings that exist in the implementation and enforcement of the legislation in place are needed.

**Specific measures**: the Framework Regulation lists 17 food contact materials and articles (FCMs) which may be covered by specific measures. Out of the above 17, only 4 materials are subject to specific EU measures: plastics (including recycled plastics), ceramics, regenerated cellulose, and active and intelligent materials.

The other 13 materials listed in Annex I, the possibility remains for Member States to adopt national provisions.

While the major focus should be on the adoption of specific measures for those 13 materials not yet regulated at EU level, all relevant stakeholders point out that **shortcomings exist in the implementation and enforcement of the legislation in place**.

Members pointed out that, given the prevalence of the materials referred to on the EU market and the risk they pose to human health, the Commission should forthwith prioritise the drawing-up of specific EU measures for paper and board, varnishes and coatings, metals and alloys, printing inks and adhesives.

The report noted that special attention needs to be paid to those food contact materials – whether directly or indirectly in contact with food – with a higher risk of migration, such as materials surrounding liquids and high-fat foods, and to materials that are in contact with food for a long period of time.

Members urged the Commission, when drawing up the measures required, to take account of the European Implementation Assessment conducted by the European Parliament's Research Service (DG EPRS) and of the national measures which are already in force or are being prepared.

**Risk assessment**: aware of the important role played by EFSA (European Food and Safety Authority) in the risk assessment of substances for use in FCMs regulated by specific measures; Members called on the Commission to **increase the level of funding for EFSA**. They called on EFSA and the European Chemicals Agency (ECHA) to cooperate and coordinate their work more closely.

The report stressed the need to:

• continue with further scientific research into **non-intentionally added substances** ('NIAS') as, in contrast to known hazardous substances, their identity and structure, especially in plastics, are often unknown;

• extend the concept of vulnerable groups to **pregnant and breastfeeding women** and to include the potential effects of low-dose exposure and non-monotonic dose responses in the risk assessment criteria.

Members regretted that EFSA, in its current risk assessment procedure, does not take account of the socalled '**cocktail effect**' or the effect of multiple concurrent and cumulative exposures from FCMs and other sources, which can cause adverse effects even if levels of the individual substances in the mixture are low. They exhorted the EFSA to do so in future.

The Commission is called upon to ensure:

- ensure coherence between the regulations on FCMs and **biocidal products** and to clarify the roles of ECHA and EFSA in this respect;
- better coordination and a more **coherent approach between the REACH and FCM legislation**, in particular as regards substances classified as CMRs (categories 1A, 1B and 2) or SVHCs (extremely concerning) under REACH.

**Traceability**: Members recommended that all FCMs, whether harmonised or non-harmonised, are accompanied by a declaration of conformity (DoC) and the appropriate documentation. They regretted, however, that, even when they are mandatory, DoCs are not always available for enforcement purposes, and their quality is not always high enough to ensure that they are a reliable source of compliance documentation.

The report insisted that imported FCMs from third countries must conform to EU standards, thus safeguarding public health and ensuring fair competition.

The Commission is called upon to establish mandatory labelling of the intended presence of **nanomaterials** in FCMs and to establish mandatory labelling of the composition of the FCMs.

**Compliance, enforcement and controls**: Members stressed the importance of developing EU guidelines for FCMs which would facilitate a harmonised and uniform implementation and better enforcement in the Member States. Other non-legislative policy options, such as the experience of industry self-assessment, should supplement measures to improve the enforcement of the Framework Regulation on FCMs.

The Commission are called upon to ensure that the Member States that have not already done so impose an obligation on all companies producing or importing Food Contact Materials to **officially register their business activity**.

Member States should **increase the frequency and efficiency of official controls**, based on the risk of non-compliance as well as on the health risks involved.

Lastly, the report called for more effective cooperation and coordination between the Member States and the Commission on the **early warning system** for foodstuffs and feedingstuffs, so that risks to public health can be dealt with quickly and effectively.