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DRAFT REPORT

on the implementation of the Food Contact Materials Regulation (Regulation (EC) No 1935/2004)
(2015/2259(INI))

Committee on the Environment, Public Health and Food Safety

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MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

on the implementation of the Food Contact Materials Regulation (Regulation (EC) No 1935/2004)
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The European Parliament,

– having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC[1],

– having regard to Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food[2],

– having regard to Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food[3],

– having regard to the European Implementation Assessment on 'Food Contact Materials - Regulation (EC) 1935/2004' of May 2016 carried out by the European Parliamentary Research Service[4],

– having regard to the proceedings of the workshop on 'Food Contact Materials - How to Ensure Food Safety and Technological Innovation in the Future?', held on 26 January 2016 at the European Parliament'[5],

– having regard to Rule 52 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A8-0000/2016),

A. whereas Regulation (EC) No 1935/2004 ('the Framework Regulation') sets out general safety requirements for all food contact materials (FCMs) in order to ensure that substances migrating from the material into the food concerned do not endanger human health or change the composition or characteristics of the food itself;

B. whereas Annex I to the Framework Regulation lists 17 food contact materials and articles (FCMs) which may be covered by specific measures;

C. whereas 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;

[1] OJ L 338, 13.11.2004, p. 4.
[2] OJ L 384, 29.12.2006, p. 75.
[3] OJ L 12, 15.1.2011, p. 1.
[4] PE 581.411
[5] PE 578.967

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

E. whereas materials not regulated by specific EU measures can pose a risk to public health and give rise to loss of consumer trust, legal uncertainty and increased compliance costs for operators; whereas the lack of uniform measures is detrimental to the smooth functioning of the internal market and hampers the drive towards a circular economy;

F. whereas specific measures should be based on scientific evidence; whereas several scientific unknowns remain and more research is thus needed;

Implementation of EU legislation on FCMs successes and gaps

1. Acknowledges that the Framework Regulation constitutes a solid legal basis, the objectives of which remain relevant;

2. Underlines that, while the major focus should be on the adoption of specific measures for those 13 materials not yet regulated at EU level, shortcomings exist in the implementation and enforcement of the legislation in place;

3. Awaits the upcoming review by the Commission's Joint Research Centre of the national provisions adopted by Member States for non-harmonised materials; calls on the Commission to use this review as a starting-point for drawing up the required measures;

4. Believes that, given the prevalence of the materials referred to on the EU market and the risk they pose to human health, the Commission should prioritise the drawing-up of specific EU measures for paper, board, coatings, inks and adhesives;

5. Is convinced that, in light of the EU's focus on moving towards a circular economy, specific measures at EU level should also be proposed for recycled paper and board;

Risk assessment

6. Is aware of the important role played by the European Food Safety Authority (EFSA) in the risk assessment of substances for use in FCMs regulated by specific measures; recognises the costs involved in the risk assessment of a particular substance and EFSA's limited resources; calls on the Commission, therefore, to increase the level of funding for EFSA;

7. Recognises that in order to properly assess the risks of FCMs, it is necessary to take into account both substances used in their manufacture and processing and non-intentionally added substances ('NIAS'), including impurities from the intentionally added substances and other substances resulting from chemical reactions; acknowledges that, to this end, starting substances must be clearly indicated to EFSA and to the relevant authorities in the Member States; stresses, accordingly, the importance of cooperation between scientific bodies/laboratories, and welcomes EFSA's intention to focus more

on finished materials and articles and the manufacturing process, rather than on the substances used[6];

8. Regrets that EFSA, in its current risk assessment procedure, does not take account of the so-called 'cocktail effect' or multiple exposures, and urges EFSA to do so in future; also urges the Commission to consider this when determining migration limits that are considered safe for human health;

9. Calls on the Commission to ensure better coordination between REACH and FCM legislation, especially as regards substances classified as SVHCs under REACH, and to ensure that harmful substances phased out under REACH are also phased out in FCMs;

10. Welcomes the fact that the Commission has finally announced its plan to introduce a migration limit of 0.05 mg/kg for Bisphenol A (BPA) for packaging and containers made of plastic, as well as for varnishes and coatings used in metal containers; considers this an improvement compared to the current migration limit of 0.6 mg/kg for BPA in plastic; regrets that this migration limit does not apply to all FCMs;

11. Supports research and innovation initiatives that seek to develop new substances for use in FCMs that are proven to be safe for human health;

Traceability

12. Believes that a Declaration of Compliance (DoC) can be an effective tool for ensuring that FCMs are compliant with the relevant rules, and recommends that all FCMs, whether harmonised or non-harmonised, are accompanied by a DoC and the appropriate documentation, as is currently the case for FCMs for which specific measures have been adopted;

13. Regrets, however, that, even when they are mandatory, DoCs are not always available for enforcement purposes, and that where they are available the quality of DoCs is not always high enough to ensure that they are a reliable source of compliance documentation;

14. Calls for the traceability and compliance of FCMs imported from third countries to be enhanced by means of a requirement calling for proper and complete identification documents and DoCs; insists that imported FCMs must conform to EU standards, thus safeguarding public health and ensuring fair competition;

Enforcement and controls

15. Expresses its concern that the level of enforcement of the legislation on FCMs varies greatly across the EU; highlights the importance of developing EU guidelines for FCMs which would facilitate a more uniform implementation and better enforcement in the Member States;

[6] http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4357.pdf

16. Recommends the development of a single EU standard for analytical testing in order to ensure that FCMs are tested by companies and competent authorities across the EU using one and the same method;

17. Stresses that it is the responsibility of each Member State to carry out controls on companies that produce or import FCMs; regrets, however, that some Member States do not impose the requirement for companies to register their business activity, thereby allowing such companies to circumvent conformity controls; calls on the Commission to revise the Framework Regulation, so as to require that Member States impose an obligation on all companies producing or importing FCMs to officially register their business activity;

18. Calls on the Member States to carry out controls more efficiently, on the basis of the percentage of food concerned and the length of time it has been in contact with the material in question, as well as type of FCM, temperature and any other relevant factors;

19. Insists on the need for Member States to ensure that they have the necessary staff trained to perform uniform and robust controls;

20. Instructs its President to forward this resolution to the Council, the Commission and the governments and parliaments of the Member States.

EXPLANATORY STATEMENT

Food contact materials (FCMs) are largely used in everyday life in the form of food packaging, kitchen utensils, tableware, etc. When put in contact with food, and depending on their composition and properties, the different materials may behave differently, transferring their constituents to the food. In such cases, chemicals emanating from FCMs may endanger human health or adversely change the composition of the foodstuffs. As it is estimated that food is one of the most important routes of human exposure to chemicals, food contact materials are subject to legally binding rules at EU level, which are currently laid down in Framework Regulation (EC) No 1935/2004. The legislation seeks to safeguard a high level of protection for consumers, while at the same time ensure the effective functioning of the internal market for FCM goods.

The regulation sets out general safety requirements that are applicable to all possible food contact materials and articles; it also foresees the possibility for adopting specific measures for the seventeen materials listed in Annex 1 to the Framework Regulation. So far, specific measures have been adopted at EU level for only four FCMs: plastic (including recycled plastic), ceramics, regenerated cellulose and active and intelligent materials.

For the other FCMs, Member States may adopt specific measures at national level. Some Member States have done so for the more widely used FCMs (paper and board, metals and alloys, glass, coatings, silicones, rubbers, and printing inks), but there are still many gaps.

This gives rise to a situation where the specific measures adopted by one Member State at national level, may differ from those of another Member State, creating different standards for product safety. Furthermore, the absence of specific EU measures for the majority of food contact materials listed in Annex I of Regulation (EC) No 1935/2004 leads to internal market barriers, with increased costs in compliance – which are often passed on to consumers - and a loss of competitiveness and innovation. Complying with different national rules is neither efficient nor effective in achieving the objectives of the legislation.

The Joint Research Centre of the European Commission is currently carrying out a study to provide a comprehensive overview of the current situation concerning FCMs for which no specific measures are in place at EU level.

On 26 January 2016, at the request of the European Parliament's Committee on the Environment, Public Health and Food Safety, a Workshop was held on 'Food Contact Materials – How to ensure food safety and technological innovation in the future?' in the European Parliament.

In May 2016, the European Parliament's Research Service (DG EPRS) published an extensive study on the implementation of Regulation (EC) No 1935/2004 ('European Implementation Assessment'). The study summarises the results of a comprehensive survey conducted over several months. In addition to the European Commission and the European Food Safety (EFSA), 28 national competent authorities as well as a broad range of stakeholders from business, consumer, health and environmental organisations and academia participated in the survey.

One of the major outcomes of both the European Implementation Assessment and the

Workshop was the call for further harmonisation in the area of FCMs (in particular non-harmonised), by the majority of stakeholders from across all sectors.

Clearly, further harmonisation at EU level for non-harmonised materials through specific measures based on scientific evidence, would be a step in the right direction, giving priority to those materials that constitute a particular risk to human health and in bigger demand on the EU market (namely paper and board, including recycled paper and board, coatings, inks and adhesives).

In addition, the evidence collected in the past months points to the need to urgently tackle current shortcomings in the implementation and enforcement of the legislation in place. In this respect, the focus should be on four major areas: risk assessment, traceability as well as enforcement and controls of compliance.

As regards the risk assessment of harmonised FCMs that are subject to specific measures, EFSA plays a crucial role. However, considering the costs involved in the risk assessment of particular substances, EFSA's resources are limited. In order to reduce the time needed to carry out a risk assessment and thus increase the number of substances being assessed, an increase in the level of funding of EFSA's activities in this area is deemed necessary.

In contrast, for the thirteen non-harmonised FCMs that are not subject to specific measures at EU level, the relevant authorisation procedures (including risk assessment) established at national level, would apply, if indeed they are in place. Given that EFSA is only assessing the risk of substances used in harmonised FCMs, testing methods applied by other risk assessors (businesses, national laboratories etc.), should also be streamlined, so that there are uniform safety standards in place (for analytical testing, fixed maximum limits for substances and standard conditions of use). This would also reduce costs for both businesses and consumers.

According to the EPRS study and discussions held at the Workshop, a major challenge identified is that a number of substances present in FCMs is currently not being assessed. In particular, this is the case for the so-called 'non-intentionally added substances '('NIAS') which are impurities from the intentionally added substances or substances resulting from chemical reactions (such as decomposition products or by-products formed during the production process), that are present in the finished material. To some extent, the presence of NIAS in FCMs can be predicted, but this is only possible if the intentionally added substances, the impurities and the processing conditions are known. For these reasons, it is important that complete information is provided by FCM manufacturers/processors, and that there is good cooperation between scientific bodies and laboratories throughout the Member States.

It should also be noted that in its current risk assessment procedure, EFSA does not take into account the so-called 'cocktail effect' (resulting from chemicals with similar toxicological endpoints acting together) and multiple exposures (resulting from chemicals – even in low doses – from different sources). This should, however, be looked at by EFSA in the future. In accordance with one of the main objectives of Regulation (EC) No 1935/2004, namely to protect human health, the Commission should also consider the consequences of 'cocktail effects' and multiple exposures when determining migration limits that are considered safe for human health.

Another issue that needs to be strengthened and improved in the current legislation is

traceability. The traceability of all FCMs should be ensured throughout the supply chain in order to facilitate proper controls.

For stakeholders, a key instrument for ensuring traceability is the so-called 'Declaration of Compliance' which certifies that a FCM meets the required standards. According to the framework regulation, the DoC must accompany all harmonised FCMs with the relevant information, in order to allow for reliable controls and traceability. In practice, however, DoCs are not always available for enforcement purposes, and, whenever available, the quality (i.e. the accuracy and completeness) of the DoC is not always good enough so as to ensure that they are a reliable source of compliance documentation.

The same standards for traceability and compliance must apply to FCMs imported from third countries. However, as for FCM's traded within the EU, evidence shows that in many Member States today, documentation that should accompany FCMs marketed in the EU is often either unavailable or incomplete.

In relation to controls, it would appear that only some Member States carry out controls regularly, in accordance with Regulation 882/2004 on official controls on food and feed, while others carry out controls from time to time. Consequently, differences in the intensity of controls for one and the same FCM exist across the EU. A further finding is that some Member States do not even require those companies producing or importing FCMs to officially register their business activity, which is a major obstacle to the enforcement of proper controls.

In conclusion, action at EU level is needed to address the lack of EU specific measures and the gaps in risk assessment, traceability, compliance and control. The Rapporteur calls on the Commission to revise the current regulatory framework based on the policy recommendations contained in this report, in order to facilitate the implementation of the legislation and better achieve its objectives, which are to safeguard and protect consumer health and ensure the effective functioning of the internal market.