



Procedure file

Basic information	
INI - Own-initiative procedure	2015/2259(INI)
Implementation of the Food Contact Materials Regulation (EC) No 1935/2004	Procedure completed
See also Regulation (EC) No 1935/2004 2003/0272(COD)	
Subject 4.60.04.04 Food safety	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety		02/09/2015
		S&D SCHALDEMOSE Christel	
		Shadow rapporteur	
		PPE COLLIN-LANGEN Birgit	
		ECR NICHOLSON James	
		ALDE JÄÄTTEENMÄKI Anneli	
		GUE/NGL ECK Stefan	
		Verts/ALE HÄUSLING Martin	
		EFDD PEDICINI Piernicola	
		ENF D'ORNANO Mireille	
European Commission	Commission DG Health and Food Safety	Commissioner ANDRIUKAITIS Vytenis Povilas	

Key events			
29/10/2015	Committee referral announced in Parliament, 1st reading/single reading		
12/07/2016	Vote in committee, 1st reading/single reading		
18/07/2016	Committee report tabled for plenary, single reading	A8-0237/2016	Summary
05/10/2016	Debate in Parliament		
06/10/2016	Results of vote in Parliament		
06/10/2016	Decision by Parliament, 1st reading/single reading	T8-0384/2016	Summary
06/10/2016	End of procedure in Parliament		

Technical information	
Procedure reference	2015/2259(INI)
Procedure type	INI - Own-initiative procedure
Procedure subtype	Implementation

	See also Regulation (EC) No 1935/2004 2003/0272(COD)
Legal basis	Rules of Procedure EP 54
Modified legal basis	Rules of Procedure EP 159
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/8/03960

Documentation gateway

Committee draft report	PE575.317	26/04/2016	EP	
Amendments tabled in committee	PE584.109	07/06/2016	EP	
Committee report tabled for plenary, single reading	A8-0237/2016	18/07/2016	EP	Summary
Text adopted by Parliament, single reading	T8-0384/2016	06/10/2016	EP	Summary
Commission response to text adopted in plenary	SP(2017)67	29/03/2017		

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 [Framework Regulation \(EC\) No 1935/2004](#) 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 Parliaments 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 so-called 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.

2015/2259(INI) - 06/10/2016 Text adopted by Parliament, single reading

The European Parliament adopted by 559 votes to 31, with 26 abstentions a resolution on the implementation of the Food Contact Materials (FCMs) Regulation ((EC) No 1935/2004).

Members acknowledged that the [Framework Regulation \(EC\) No 1935/2004](#) 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.

Successes and gaps of the implementation of EU legislation: Members underlined that, 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.

Taking account of the risks they pose to human health, the Commission should prioritise the drawing-up of specific EU measures for paper and board, varnishes and coatings, metals and alloys, printing inks and adhesives.

Given the risk of migration of mineral oils into food from food contact materials and articles made of paper and board, Parliament supported, pending the adoption of specific measures and a possible ban on mineral oils in inks, further research aimed at preventing such migration.

Members are of the opinion that the adoption of further specific measures at EU level would encourage business operators to develop safe reusable and recycled FCMs, thereby contributing to the EUs efforts to establish a more effective circular economy.

The Commission is urged, when drawing up the measures required, to take account of the European Implementation Assessment conducted by the European Parliamentary Research Service (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, Parliament called on the Commission to increase the level of funding for EFSA. It called on EFSA and the European Chemicals Agency (ECHA) to cooperate and coordinate their work more closely.

The resolution 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 so-called 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;
- ensure that harmful substances phased out under REACH are also phased out in FCMs.

Parliament also called on the Commission to consider identifying Bisphenol A (BPA) as one of the substances classified as a substance of very high concern (SVHC).

Traceability: Parliament recommended that all FCMs, whether harmonised or non-harmonised, are accompanied by a declaration of conformity (DoC) and the appropriate documentation. It 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: Parliament 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 is 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, Parliament 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.