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REPORT

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

Committee on the Environment, Public Health and Food Safety

Rapporteur: Christel Schaldemose

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MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

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

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/EEC¹,
- 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 food²,
- having regard to Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food³,
- 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 Service⁴,
- 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 Parliament⁵,
- having regard to the Commission State of the Art Report on Mixture Toxicity⁶,
- having regard to the Communication from the Commission to the Council on the combination effects of chemicals – Chemical mixtures (COM(2012)0252),
- having regard to the conclusions adopted by the Council of Environment Ministers on 22 December 2009 on the combination effects of chemicals⁷,
- having regard to Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 ‘Living well, within the limits of our planet’, which, inter alia, recognises the need for the EU to address combination effects of chemicals and safety concerns related to endocrine disruptors in all relevant Union legislation⁸,
- having regard to an assessment of the ‘State of the science of endocrine disrupting

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

⁶ Kortenkamp 2009. http://ec.europa.eu/environment/chemicals/effects/pdf/report_mixture_toxicity.pdf

⁷ <http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%2017820%202009%20INIT>

⁸ 7th Environment Action Programme: OJ L 354, 28.12.2013, p. 171, <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013D1386>

chemicals – 2012’, prepared for the United Nations Environment Programme (UNEP) and the World Health Organisation (WHO)¹,

- having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (‘the REACH Regulation’)²,
 - 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 (A8-0237/2016),
- A. whereas Regulation (EC) No 1935/2004 (‘the Framework Regulation’) sets out general safety requirements for all food contact materials and articles which are intended to come into contact directly or indirectly with food in order to ensure that substances do not migrate into food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties;
- 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;
- D. whereas there is a strong need for revision of certain specific EU measures, in particular Council Directive 84/500/EEC on ceramics;
- E. whereas for the other 13 materials listed in Annex I, the possibility remains for Member States to adopt national provisions;
- F. whereas many Member States have already introduced or are currently working on different measures for the remaining FCMs; whereas with regard to these national measures the principle of mutual recognition does not work, and the effective functioning of the internal market as well as a high level of health protection, as envisaged by the Framework Regulation and the Treaties, cannot, therefore, be ensured;
- G. 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 – which are often passed on to consumers further down the supply chain – thus hampering competitiveness and innovation; whereas, according to the European Implementation Assessment of May 2016, carried out by the European

¹ <http://www.who.int/ceh/publications/endocrine/en/>

² OJ L 396, 30.12.2006, p. 1.

Parliamentary Research Service (EPRS), there is a broad consensus among all relevant stakeholders that the lack of uniform measures is detrimental to public health and the protection of the environment, and to the smooth functioning of the internal market;

- H. whereas the ‘Better Regulation’ principles should not delay any measure aimed at averting or reducing potentially serious or irreversible consequences for human health and/or the environment, as compelled by the precautionary principle enshrined in the EU Treaties;
- I. whereas endocrine disruptors and genotoxic substances in FCMs are particularly problematic for both public health and the environment; whereas endocrine-disrupting or genotoxic properties cannot currently be reliably predicted from the chemical composition, and therefore biotesting should be encouraged as an optional premonitory measure to ensure the safety of chemically complex FCMs; whereas research on the development of both analytical and toxicological testing should be encouraged to ensure robust and cost-effective safety assessments of FCMs for the benefit of consumers, the environment and manufacturers;
- J. whereas deleterious microorganisms (pathogenic or spoilage) that may be present as contaminants of FCMs, and the biocides that may be consequently used to reduce their number, also pose a risk to public health;
- K. whereas some foods are in contact for long periods with a wide range of packaging materials;
- L. whereas more effective coordination of all the provisions which have a bearing on the use of FCMs could help to better protect consumers’ health and reduce the impact of FCMs and, in particular, packaging materials on the environment;
- M. whereas more effective coordination of all the provisions which affect FCMs, including the REACH Regulation, would make the circular economy more effective;
- N. whereas specific measures should be based on scientific evidence; whereas several scientific unknowns remain and more research is thus needed;
- O. whereas according to the European Food Safety Authority (EFSA), nanotechnology and nanomaterials are a new technological development and FCMs are one sector in which the use of nanomaterials has featured; whereas the specific properties of nanomaterials may affect their toxicokinetic and toxicology profiles, but limited information is available in relation to these aspects; whereas there are also uncertainties stemming from the difficulty of characterising, detecting and measuring nanomaterials in food and in biological matrices, and from the limited availability of toxicity data and test methods;
- P. whereas health and environmental risk assessments at EU level are currently limited to the assessment of individual substances and ignore the real-life conditions of combined and cumulative exposure from different routes and product types, also known as the ‘cocktail’ or ‘mixture’ effect;
- Q. whereas according to a recommendation by the Food and Agriculture Organisation of

the United Nations (FAO)/WHO (2009)¹, exposure assessments should cover the general population, as well as critical groups that are vulnerable or are expected to have a higher level of exposure than the general population (for example infants, children);

- R. whereas the traceability of FCMs should be ensured at all stages of the supply chain in order to facilitate monitoring, the recall of defective products, consumer information and the attribution of responsibility;
- S. whereas labelling is a very direct and effective tool to inform the consumer about the characteristics of a product;
- T. whereas a horizontal approach to substances across all economic sectors provides consistency in legislation and predictability for businesses;
- U. whereas the development of uniform EU testing methods for all FCMs would contribute to a higher level of health and environmental protection across the EU;
- V. whereas introducing a safety check for pre-manufactured food contact articles could be one way of supplementing certain specific measures;

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, all relevant stakeholders point out that shortcomings exist in the implementation and enforcement of the legislation in place;
3. Anticipates 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. Urges the Commission, when drawing up the measures required, to take account of the European Implementation Assessment conducted by EPRS and of the national measures which are already in force or are being prepared;
5. Points out that, given the prevalence of the materials referred to on the EU market and the risk they pose to human health, and in order to preserve the single market for FCMs and food products alike, 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;
6. Underlines 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,

¹ Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials - EFSA Journal 2016;14(1):4357 [28 pp.]
<https://www.efsa.europa.eu/en/efsajournal/pub/4357>

such as materials surrounding liquids and high-fat foods, and to materials that are in contact with food for a long period of time;

7. Is 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 EU's efforts to establish a more effective circular economy; points out that one precondition for this would be better traceability and the phasing-out of substances in FCMs which could pose a threat to public health;
8. Underlines, in this context, that the use of FCMs made from recycled products and the reuse of FCMs should not lead to a higher number of contaminants and/or residues in the final product;
9. Is convinced that, in light of the EU's focus on moving towards a circular economy, better synergies between the Framework Regulation on FCMs and the circular economy should be developed, which should include specific measures at EU level for recycled paper and board; notes that there is a limit to the number of times that recycled paper and board products may be reused, thus requiring a steady supply of fresh wood fibres;
10. Given the risk of migration of mineral oils into food from food contact materials and articles made of paper and board, supports, pending the adoption of specific measures and a possible ban on mineral oils in inks, further research aimed at preventing such migration;
11. Supports the increase in recycling and reuse targets for all materials in the Commission proposal for a Directive amending Directive 94/62/EC on packaging and packaging waste (COM(2015)0596); reminds the Commission, however, that targets for recycling and reuse must be accompanied by adequate control measures to ensure the safety of materials entering into contact with foods;
12. Emphasises the difficult position in which small and medium-sized enterprises in the production chain find themselves, given that, in the absence of relevant legislative provisions, they are not in a position to receive or pass on information which would guarantee that their products are safe;
13. Considers it imperative that Member States should involve all relevant stakeholders in the process when specific safety requirements for FCMs are proposed;
14. Recognises that the current paradigm for evaluation of safety of FCMs is insufficient, as there is a general underestimation of the role of FCMs in food contamination and a lack of information on human exposure;

Risk assessment

15. Is aware of the important role played by 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 in view of the additional work involved given the increased need for risk assessments as detailed below;

16. Calls on EFSA and the European Chemicals Agency (ECHA) to cooperate and coordinate their work more closely in an effort to make effective use of the resources available to carry out comprehensive assessments;
17. 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 used¹;
18. Emphasises the importance of further scientific research into NIAS as, in contrast to known hazardous substances, their identity and structure, especially in plastics, are often unknown;
19. Calls on the Commission to review the evidence for: (i) current assumptions made on the migration of substances through functional barriers; (ii) the 10 ppb threshold concentration for migrating substances in food that is being used by some companies and competent authorities to decide which chemicals to risk assess; (iii) the extent to which functional barriers become less effective over long storage periods, as they may only slow down migration; (iv) current assumptions on molecular size affecting chemical absorption through the intestine;
20. Calls on EFSA and the Commission to 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;
21. Regrets 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, and exhorts EFSA to do so in future; also urges the Commission to consider this effect, including over long periods of time, when determining migration limits that are considered safe for human health;
22. Calls for further scientific research into the interaction between different chemicals;
23. Further regrets that EFSA does not yet take account of the possibility of deleterious microorganisms in FCMs; urges EFSA's Panel on Biological Hazards (BIOHAZ), therefore, to examine the issue of microorganisms in FCMs through preparation of an EFSA opinion on the subject;
24. Points out that FCMs are included within the scope of Regulation (EU) No 528/2012 (the Biocidal Products Regulation, 'BPR'²), as biocides may be present in food contact materials to keep their surface free from microbial contamination (disinfectants) and to

¹ http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4357.pdf

² OJ L 167, 27.6.2012, p. 1.

have a preservative effect on the food (preservatives); notes, however, that the different types of biocides in FCMs are regulated under different legal frameworks and that, depending on the type of biocide, the risk assessment has to be carried out by ECHA or EFSA, or by both agencies;

25. Calls on the Commission to ensure coherence between the regulations on FCMs and biocidal products and to clarify the roles of ECHA and EFSA in this respect; further calls on the Commission to work on a harmonised and consolidated approach for the overall assessment and authorisation of substances used as biocides in FCMs, with a view to avoiding overlapping, legal uncertainties and duplication of work;
26. Calls on EFSA to consider the fact that food production sites were identified by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in 2009 as one critical place promoting the development of bacteria resistant to both antibiotics and biocides; points out, therefore, that FCMs containing biocides may also contribute to the occurrence of antibiotic-resistant bacteria in humans;
27. Underlines that FCMs are a significant source of human exposure to chemicals of concern, including perfluorinated compounds (PFCs) and endocrine disrupting chemicals (EDCs), such as phthalates and bisphenols, which have been linked to chronic diseases as well as reproductive problems, metabolic disorders, allergies and neurodevelopmental problems; notes that the migration of such chemicals is of particular concern in FCMs given their potential to cause harm even in extremely small doses;
28. Notes with concern the increased effect on health that substances used in FCMs can have on babies and young children;
29. Calls on the Commission to fill the safety assessment gap between the REACH and FCM legislation by ensuring that companies produce safety assessments of the human health aspects of exposure to chemicals used in FCMs during production, use and distribution; considers that this should be clarified in Regulation (EC) No 1935/2004;
30. Calls on the Commission to ensure 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 under REACH, and to ensure that harmful substances phased out under REACH are also phased out in FCMs; stresses that, in order to ensure that any danger to public health can be ruled out, the Commission must periodically inform and update Parliament and the Council if certain substances of concern (such as SVHCs, CMRs, bio-accumulative chemicals or certain categories of endocrine disrupting chemicals) that are banned or phased out under REACH or any other legislation are still used in FCMs; calls on the Commission to consider identifying Bisphenol A (BPA) as one of the substances classified as an SVHC;
31. Notes the publication by the Commission, on 15 June 2016, of scientific criteria for determining the endocrine-disrupting properties of active substances used in biocidal products and plant protection products; underlines, however, the need for horizontal criteria for all products, including FCMs, and calls on the Commission to present such criteria without delay; calls for these criteria, once in force, to be considered in the risk

assessment procedure of FCMs;

32. Welcomes the fact that, following the recent EFSA opinion, the Commission has finally announced its plan to introduce a migration limit of 0.05 mg/kg for 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, owing to a lack of specific measures, there are no corresponding migration limits for all FCMs;
33. Acknowledges, on the basis of the 2015 Science and Policy Report by the Commission's Joint Research Centre, the issue of heavy metals migrating into food; understands that the Commission is reviewing the limits for lead and cadmium in Council Directive 84/500/EEC on ceramics; strongly urges the Commission to come up with a legislative proposal introducing lower limits for the release of cadmium and lead and regrets that the revision of Directive 84/500/EEC has not yet been discussed in Parliament and the Council;
34. Supports research and innovation initiatives that seek to develop new substances for use in FCMs that are proven to be safe for human health; stresses, however, that for the time being, any safer alternatives should not include Bisphenol S (BPS) as a substitute for Bisphenol A (BPA), as BPS may have a toxicological profile similar to BPA¹;
35. Supports, in particular, further research into nanomaterials, as there is still scientific uncertainty regarding the effects and migration capability of these materials and their effect on human health; believes, therefore, that nanomaterials should be subjected to authorisation for use not only in plastic materials but in all FCM materials, and should be assessed not only in their bulk form;
36. Points out that market barriers, and in particular petitioning for authorisations under differing national rules, result in loss of opportunities for food safety improvement via innovation;

Traceability

37. 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; believes that conditions of use should be better reflected in the relevant declarations of compliance;
38. 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;
39. Calls for the traceability and compliance of FCMs imported from third countries to be

¹ Committee for Socio-economic Analysis (SEAC), Opinion on an Annex XV dossier proposing restrictions on Bisphenol A, p.13. http://www.echa.europa.eu/documents/10162/13641/bisphenol_a_seac_draft_opinion_en.pdf

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;

40. Calls on the Commission to establish mandatory labelling of the intended presence of nanomaterials in FCMs and to establish mandatory labelling of the composition of the FCMs used for organic products and products intended for critical groups;

Compliance, enforcement and controls

41. 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 harmonised and uniform implementation and better enforcement in the Member States; to this end, underlines the importance of sharing data between Member States; believes that 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;
42. Takes the view that further harmonisation of food contact materials and articles can help to bring about a uniformly high level of public health protection;
43. Recommends the introduction of uniform EU standards for analytical testing of given categories of food contact materials and articles in order to ensure that companies and competent authorities across the EU carry out tests using the same method; notes that the introduction of uniform testing methods would guarantee the same treatment of FCMs throughout the internal market, thus ensuring improved monitoring standards and higher protection levels;
44. Stresses that it is the responsibility of each Member State to carry out controls of 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 ensure that those Member States that have not already done so impose an obligation on all companies producing or importing FCMs to officially register their business activity in accordance with the revision of Regulation (EC) No 882/2004; recognises the existence of suitable registration mechanisms in several Member States, which can serve as examples of best practice;
45. Calls on the Member States to increase the frequency and efficiency of official controls, based on the risk of non-compliance as well as on the health risks involved, taking into account the quantity of food, the intended consumer and the length of time it has been in contact with the FCM, as well as the type of FCM, temperature and any other relevant factors;
46. Insists on the need for Member States to ensure that they put in place the necessary staff and equipment to perform uniform, robust and systematic controls, as well as a system of dissuasive penalties for cases of non-compliance, in accordance with the revision of Regulation (EC) No 882/2004;
47. Calls 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;

48. Calls on the Commission to study further the approach based on safety checks for pre-manufactured food contact articles or other approval procedures for food contact articles;
49. Welcomes the Commission's 'Better Training for Safer Food' platform; calls for its activities to be expanded;
50. 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.

RESULT OF FINAL VOTE IN COMMITTEE RESPONSIBLE

Date adopted	12.7.2016
Result of final vote	+: 61 -: 3 0: 0
Members present for the final vote	Marco Affronte, Margrete Auken, Pilar Ayuso, Zoltán Balczó, Catherine Bearder, Ivo Belet, Simona Bonafè, Biljana Borzan, Lynn Boylan, Cristian-Silviu Buşoi, Soledad Cabezón Ruiz, Nessa Childers, Alberto Cirio, Birgit Collin-Langen, Mireille D'Ornano, Miriam Dalli, Seb Dance, Jørn Dohrmann, Ian Duncan, Stefan Eck, Bas Eickhout, Eleonora Evi, José Inácio Faria, Karl-Heinz Florenz, Francesc Gambús, Elisabetta Gardini, Gerben-Jan Gerbrandy, Jens Gieseke, Julie Girling, Sylvie Goddyn, Françoise Grossetête, Andrzej Grzyb, Anneli Jäätteenmäki, Jean-François Jalkh, Karin Kadenbach, Kateřina Konečná, Giovanni La Via, Peter Liese, Norbert Lins, Valentinas Mazuronis, Susanne Melior, Miroslav Mikolášik, Massimo Paolucci, Gilles Pargneaux, Piernicola Pedicini, Pavel Poc, Frédérique Ries, Michèle Rivasi, Annie Schreijer-Pierik, Renate Sommer, Dubravka Šuica, Tibor Szanyi, Nils Torvalds, Jadwiga Wiśniewska, Damiano Zoffoli
Substitutes present for the final vote	Nikos Androulakis, Paul Brannen, Nicola Caputo, Martin Häusling, Merja Kyllönen, Christel Schaldemose, Keith Taylor
Substitutes under Rule 200(2) present for the final vote	Jiří Maštálka, Maurice Ponga