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Food Contact Materials - Regulation (EC) 1935/2004

European Implementation Assessment

STUDY

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Food Contact Materials
Regulation (EC) 1935/2004

European Implementation Assessment Study

On 16 July 2015, the coordinators for the European Parliament's Committee on Environment, Public Health and Food Safety requested authorisation to draw up an implementation report on the Food Contact Materials Regulation (EC) No 1935/2004.

This in-house supporting study has been produced by the Ex-Post Impact Assessment Unit of the Directorate for Impact Assessment and European Added Value, within the European Parliament's Directorate-General for Parliamentary Research Services. It looks at the implementation of the relevant legal framework regulating food contact materials at EU level, and Regulation (EC) No 1935/2004 in particular. The research paper builds on stakeholders' perceptions of implementation as shared within a survey conducted by the Unit between December 2015 and February 2016. We would like to express our gratitude to all stakeholders who participated in the survey thus helping to underpin EU evidence-based policy-making in the field of food safety.

Abstract

Food contact materials (FCMs) are widely used in everyday life in the form of food packaging, kitchen utensils, tableware, etc. When put in contact with food, the different materials may behave differently and transfer their constituents to the food. Thus, if ingested in large quantities, FCM chemicals might endanger human health, or change the food itself. Therefore, food contact materials are subject to legally binding rules at EU level, currently laid down in Regulation (EC) No 1935/2004 which aims at ensuring FCM safety but also the effective functioning of the internal market in FCM goods.

The regulation sets up a general safety requirement applicable to all possible food contact materials and articles, and envisages a possibility for the adoption of specific safety requirements (i.e. further harmonisation at EU level) for seventeen FCMs listed in Annex I to Regulation (EC) No 1935/2004. So far, specific safety requirements have been adopted only for four FCMs: plastics (including recycled plastics), ceramics, regenerated cellulose and so-called active and intelligent materials. Where specific requirements have not been adopted at EU level, Member States could adopt such measures at national level, which is the case for several widely used FCMs, such as: paper & board, metals & alloys, glass, coatings, silicones, rubbers, printing inks etc.

However, as reported by the majority of stakeholders participating in this survey, the lack of specific measures at EU level for some food contact materials/articles negatively impacts the functioning of the internal market for the relevant material/article and its food safety. Stakeholders - across businesses, consumers, environmental and health NGOs, researchers, as well as Member States' competent authorities - are in favour of specific measures at EU level for the FCMs that are not yet harmonised at EU level.

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bw - body weight

BADGE - bisphenol A diglycidyl ether, also abbreviated as BPA

BFDGE - bisphenol F diglycidyl ether, also abbreviated as BPFNOGE - novolac glycidyl ether

CEN - European Committee for Standardization

CMR - substances that are carcinogenic, mutagenic, or toxic for reproduction

CoE - Council of Europe

COM - European Commission

DA - delegated act

DoC - declaration of compliance (under Article 16 of Regulation (EC) No 1935/2004)

DG SANTE - European Commission, Directorate General for Health and Food Safety

EDCs - endocrine disrupting chemicals

EFSA - European Food Safety Authority (EU Agency)

ENVI - Committee of the European Parliament on Environment, Public Health and Food Safety

EP - European Parliament

ESCO - Scientific Cooperation Projects (EFSA's ESCO Working Group on non-plastic food contact materials)

EC - European Community

EU - European Union

EU-RL FCM - European Union Reference Laboratory for Food Contact Materials

FCM(s) - food contact material(s)

FDA - Food and Drugs Authority of the United States of America

FVO - DG SANTE (Directorate Health and Food Audit and Analysis, ex-Food and veterinary office (FVO))

GMP – good manufacturing practice

IIA - interinstitutional agreement

ISO - International Organization for Standardization

JRC - Joint Research Centre of the European Commission

LWP - lightweight packaging

MEP - Member of the European Parliament

MMM - multilayer multi-materials

NIASs - non-intentionally added substances

ORPI - oligomers, reaction and degradation products and impurities

PEMSAC - Platform of European Market Surveillance Authorities in Cosmetics

PET/PETE - polyethylene terephthalate

PBTs - persistent, bio-accumulative and toxic substance(s)

vPvBs - very persistent and bio-accumulative

PFCs - perfluorinated compounds

ppm - parts per million

ppb - parts per billion

PVC - Polyvinyl chloride

REACH - registration, evaluation, authorisation and restriction of chemicals under Regulation (EC) No 1907/2006)

R&D - research and development

REFIT - Regulatory Fitness and Performance Program of the European Commission'

SVHC - substances of very high concern

SMEs - small and middle-size enterprises

TPE - thermoplastic elastomers

TFEU - Treaty on the Functioning of the European Union

Executive summary

Food contact materials (FCMs) are widely 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 and transfer their constituents to the food. Thus, if ingested in large quantities, FCM chemicals might endanger human health, or change the food itself. Therefore, since 1976, food contact materials have been subject to legally binding rules at EU level. The main objectives of EU FCM policy are to ensure the effective functioning of the internal market of FCM goods and to secure a high level of protection of human health and the interests of consumers.

The current EU FCM legal framework lays down a *general* safety requirement aimed at ensuring that the substances migrating from the material into the food do not endanger human health or change the food itself. This general safety requirement applies to all possible food contact materials/articles. The possibility for adoption of *specific* safety requirements ('specific measures') for individual food contact materials[1], i.e. further harmonisation at EU level, does exist. However, so far, only a few specific measures - such as for plastics and ceramics, for example - have been adopted at EU level. Specific safety requirements are by nature implementing measures; therefore the existence or absence of EU specific measures for some food contact materials directly impacts the implementation of the general safety requirement mentioned above and the achievement of market and safety objectives. In particular, the lack of EU specific measures for some FCMs leaves the possibility for EU Member States to adopt such measures at national level, which, as revealed by this study, creates internal market barriers without necessarily securing FCM safety.

This in-house European Implementation Assessment summarises the results of a stakeholders' survey conducted by the EPRS Ex-Post Impact Assessment Unit between December 2015 and February 2016. It aims to assess the implementation of existing EU FCM rules, and, in particular, framework Regulation (EC) No 1935/2004 - thus supporting the work of the European Parliament's Committee on Environment, Public Health and Food Safety on a dedicated Implementation Report on that legislation.

Based on stakeholders' perceptions, **problems inherent to the EU FCM legal framework itself and to the implementation of relevant rules were identified**.

For a large majority of stakeholders (across almost all categories), **the current legal framework regulating food contact materials at EU level is not complete.** The lack of specific measures for the majority of food contact materials[2] directly impacts the implementation of the general safety requirement laid down in Regulation (EC) No 1935/2004 and the achievement of its objectives. In particular, as reported by stakeholders, for non-harmonised materials effective functioning of the internal market and consumer safety could not be fully ensured.

Indeed, this lack of specific measures for some food contact materials results in internal market barriers, increased compliance costs - which are eventually covered by end

[1] Listed in Annex I to Regulation (EC) No 1935/2004.
[2] Listed in Annex I to Regulation (EC) No 1935/2004, and for which specific measures at EU level could be adopted.

consumers - loss of competitiveness and innovation, and delayed market access for businesses. Market barriers, and in particular, petitioning for authorisations under differing national rules, also result in loss of opportunities for food safety improvement via innovation. The lack of uniform EU safety standards for non-harmonised FCMs (substances) also means that uniform safety across the EU could not be ensured in practice. Thus, without EU specific measures for some FCMs, the general EU FCM safety requirement, established by framework Regulation (EC) No 1935/2004, could not be fully complied with and enforced.

Stakeholders recommend the adoption of specific measures for the articles and materials which have not yet been harmonised at EU level. Generally, stakeholders are aware that full harmonisation of all currently non-harmonised FCMs is a time-consuming process. Therefore, they recommend the adoption of specific measures for some of the materials listed in Annex I to the framework Regulation which they consider to be a matter of priority. Paper & board is the 'number one' candidate for harmonisation at EU level, as recommended by the majority of stakeholders participating in the survey.

As a general trend, stakeholders who are in favour of further EU level harmonisation recommend that **EU specific measures should establish** a single standard for analytical (testing) methods, such as composition determination, migration testing, risk assessment, but also specific methods for compliance enforcement, thus ensuring that the relevant FCM is tested by companies and competent authorities across the EU with one and the same method. Furthermore, the EU single standard for analytical (testing) methods should be specific for each FCM, thus reflecting its unique properties and avoiding situations where non-harmonised FCMs are tested with methods developed for harmonised FCMs, which could lead to misleading and debatable test results.

In their responses, stakeholders (across most categories) insist that the adoption of **specific measures at EU level should be based on scientific evidence**. However, as a general rule, FCMs are often associated with research challenges. Thus stakeholders have come up with recommendations aimed at overcoming issues of major concern such as, for example, the proper identification of both starting substances (i.e. those used at the beginning of FCM manufacturing/procession) and also the so-called 'non-intentionally added substances' (created as a result of chemical reactions and the presence of which in finished food contact materials and articles remains unknown), etc. In particular, cooperation between the key players possessing FCM scientific knowledge, aimed at overcoming the identified research challenges, is a common recommendation.

For stakeholders, **the implementation of existing EU FCM rules is also associated with problems**. In particular, day-to-day implementation problems concern traceability and official controls.

In terms of traceability, implementation problems reported by stakeholders (mainly across businesses and competent authorities) are related mostly to the availability and quality (accuracy, completeness and hence reliability) of compliance documentation (also for imported FCM products) which, according to stakeholders, hinders proper traceability. Thus, among other things, both businesses and competent authorities recommended dedicated training aimed at improving each other's compliance and enforcement capacities, and improvement of traceability of imported FCM products.

As far as official controls are concerned, stakeholders' responses suggested that control activities are not carried out with the same intensity across Member States. In particular, the majority of businesses and half of the competent authorities responding share a common perception that controls are carried out 'from time to time on a routine basis' while Regulation (EC) No 882/2004 on food and feed controls requires that controls are carried out 'regularly'. Furthermore, although this observation is based on perceptions only, the majority of businesses participating in the survey consider that there are differences in the intensity of controls for one and the same FCM across the EU. The data submitted under this survey is not enough, however, for this assumption to be proved or ruled out. Therefore, further research on the intensity of control activities, as well as pertinent traceability issues of concern, would be justified. The results of a possible future study identifying control experiences would constitute a valuable basis for the development of further legal (harmonisation) provisions but also of non-legal instruments (guidance documents) at EU level.

A **final assessment against the set of key assessment criteria** showed that the current EU FCM policy objectives were assessed as relevant to stakeholders' needs. The added value of FCM rules established at EU level was welcomed: for a large majority of stakeholders, there is no alternative to EU-level harmonisation of food contact materials. However, while the fulfilment of the criteria of effectiveness, efficiency and coherence was confirmed for FCMs harmonised at EU level, the extent to which these criteria are met by non-harmonised FCMs was questioned by stakeholders. This would suggest that further action at EU level, in terms of both legislative and non-legislative measures, might be necessary in order to meet the remaining implementation challenges.

Introduction

Human beings need food energy to survive. At some stage on its way 'from farm to fork', food has almost certainly come into contact with a storage vessel, a food preparation surface, packaging, kitchen utensil, tableware or another recipient made of 'food contact materials' (FCMs).

Food contact materials (plastics, paper, ceramics, glass, metals and alloys, etc.) are made of substances that might behave differently depending on the foodstuff with which they enter in contact. For example, acid foods can corrode metals. As a result of these chemical reactions, the food contact materials might transfer their chemical constituents into the food, a process known as 'migration of substances'. In fact, no food contact material is completely inert and so it is possible for its chemical constituents to migrate into food. The migration of FCM substances into food could bring changes in food safety (if chemicals are ingested by humans in too large quantities) and in food quality (e.g. if the transferred chemicals change the colour or odour of the food) (Castle, 2007).

These risks make it necessary for FCMs to be regulated. Until the mid-70s FCM legally binding rules were adopted only at national level. However, national rules impeded the free movement of food contact materials in the common market and created risks related to food safety. Therefore, in 1976 a first set of rules was adopted to harmonise FCM rules at Community level. The directive aimed both to remove trade barriers, ensuring equal conditions for competition, but also to protect human health. This first FCM directive laid down the **key principles** of EU FCM law which, although amended over the decades, remain in place today.

At EU level, FCMs are regulated by a complex set of rules. These consist of:

- framework Regulation (EC) No 1935/2004, which establishes general safety requirements for the manufacturing, procession and distribution of all possible FCMs, and
- a number of secondary legal acts laying down specific safety requirements ('specific measures') for individual FCMs[3].

However, currently only four FCMs (out of the seventeen for which specific safety requirements may be adopted) are subject to such 'specific measures' and detailed harmonisation at EU level, namely:

- plastics (including recycled plastics),
- ceramics,
- regenerated cellulose film, and
- active and intelligent materials.

Although not 'implementing acts'[4] as such, specific safety requirements are by nature implementing measures; therefore, **the existence or absence of specific measures for the relevant food contact materials directly impacts the implementation of the general safety requirements and the achievement of market and safety objectives.** In particular,

[3] At EU level such 'specific measures' may be adopted only for the 17 food contact materials/articles listed in Annex I to Regulation (EC) No 1935/2004.
[4] Under Regulation (EU) 182/2011, known as the new 'comitology' regulation.

the lack of EU specific measures for some of the FCMs listed in Annex I of the framework Regulation leaves the possibility for EU Member States to adopt such measures at national level.

This European Implementation Assessment is based on a **snapshot of implementation challenges as perceived and reported by relevant stakeholders**. Indeed, between December 2015 and February 2016 the EPRS 'Ex-Post Impact Assessment' Unit invited stakeholders to participate in a survey aimed at assessing the implementation of existing EU FCM rules, and framework Regulation (EC) No 1935/2004, in particular. In total, 61 relevant stakeholders - including businesses, all 28 Member States' competent authorities, EFSA, the relevant services of the European Commission, consumer, health and environmental organisations, as well as researchers - took part in the survey, thus ensuring the representativeness of the results of this EIA study.

Part 1 of the EIA study presents the current EU FCM legal framework the implementation of which is subject to assessment. **Part 2** gives details on the methodology of the survey and its representativeness. **Part 3** summarises stakeholders' responses to the relevant questions included in the survey, and outlines trends, if any. Finally, based on stakeholders' perceptions, **Part 4** assesses the identified implementation problems and impacts against the following assessment criteria for evaluations: relevance, coherence, European added value, effectiveness, efficiency, utility and complementarity - and summarises stakeholders' recommendations.

1. The EU food contact materials (FCM) policy – legal framework

1.1. Framework Regulation (EC) No 1935/2004 and relevant legal acts

The current EU food contact materials policy is based on legal regulation as the main policy instrument. The basic rules are laid down in Regulation (EC) No 1935/2004[5], commonly referred to as the 'framework Regulation'. This legal act was the successor of the two framework directives[6] that had been regulating food contact materials since 1970's.

1.1.1. Key objectives

In line with the EU General Food Safety Law[7], the rules on food contact materials, established at EU level by framework Regulation (EC) No 1935/2004, aim to:

- ensure the effective functioning of the internal market, and
- provide the basis for securing a high level of protection of human health and the interests of consumers.

1.1.2. Scope of application

The rules laid down in the regulation apply to all materials and articles, including so-called active and intelligent materials[8], which in their finished state:

- are intended to be brought into contact with food (e.g. kitchen utensils and tableware), or
- are already in contact with food and were intended for that purpose (e.g. food packaging), or
- can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use (e.g. napkins and table mats)

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[5] Regulation (EC) No 1935/2004.

[6] Directive 76/893/EEC and Directive 89/109/EEC.

[7] Regulation (EC) No 178/2002, known as the 'general EU food law' regulation.
In 2014, the Commission launched a **Fitness Check on the General Food Law Regulation**, which establishes the fundamental pillars of the food and feed law. It is a comprehensive policy evaluation assessing whether the legislative framework introduced by the General Food Law Regulation for the entire food and feed sector is '**fit for purpose**' and whether it captures and reflects policy trends of today.

[8] Article 2 (a) and (b) of Regulation (EC) No 1935/2004 defines 'active' and 'intelligent' materials/articles as follows:
'active' are the materials/articles intended to extend the shelf-life or to maintain or improve the condition of packaged food; they are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food; 'intelligent' are the materials/articles intended to monitor the condition of packaged food or the environment surrounding the food.

The rules of the framework Regulation do not apply to:

- materials and articles which are supplied as antiques;
- covering or coating materials, such as the materials covering cheese rinds, prepared meat products or fruits, which form part of the food and may be consumed together with this food;
- fixed public or private water supply equipment.

1.1.3. General safety requirements at EU level

The two main requirements as regards food contact materials and articles are laid down in Article 3 of Regulation (EC) No 1935/2004.

First, as a general rule, all food contact materials and articles should be manufactured in compliance with **good manufacturing practice**, so that, under normal and foreseeable conditions of use, they do not transfer their constituents to food in quantities that could endanger human health, bring about an unacceptable change in the composition of the food, or a deterioration of its organoleptic characteristics[9]. Article 4 of the regulation foresees special requirements as regards active and intelligent articles and materials.

Second, the labelling, advertising and presentation of a food contact material or article should not mislead the consumers.

These are the general requirements that constitute the legal basis for enforcement by the national competent authorities and apply to all possible FCMs. Furthermore, Regulation (EC) No 1935/2004 provides for the possibility for adoption of specific requirements for seventeen materials/articles listed in Annex I.

Good manufacturing practice

Good manufacturing practice is further defined in Regulation (EC) No 2023/2006 which applies to all food contact materials and all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances.

Under the GMP regulation, business operators are obliged to establish, implement and adhere to 'quality assurance' and 'quality control' systems. Detailed rules as regards processes involving the application of printing inks to the non-food contact side of a material or article are also laid down.

Several industries manufacturing, processing or distributing food contact materials have developed their material/article-specific guidelines on good manufacturing practice aimed at helping companies to ensure compliance with GMP requirements.

GMPs are a tool aimed at strengthening the self-assessment and responsibility of the manufacturers, processors and distributors of FCM goods.

[9] The 'organoleptic characteristics' of the food refer to its flavour (taste and odour) and aspect (colour and texture).

1.1.4. Specific safety requirements - further harmonisation at EU level

Article 5 (1) of framework Regulation (EC) No 1935/2004 creates the opportunity for specific requirements ("specific measures") for the individual materials and articles listed in Annex I[10] to be established, i.e. further harmonised at EU level. Among others, specific measures may include:

- lists of substances authorised for use in the manufacturing of materials and articles,
- purity standards for substances put on the positive lists,
- special conditions of use for substances on the positive lists and/or the materials and articles in which they are used,
- specific and/or overall limits on the migration of certain constituents into the food,
- basic rules for checking compliance with the harmonised rules, etc.

Authorisations for substances not yet on lists of authorised substances also take the form of specific measures.

The adoption of specific measures lies with the European Commission, which may adopt such measures but is not obliged to do so. In most cases, specific measures are adopted via the 'regulatory procedure with scrutiny' (RPS) in which the European Parliament plays a scrutiny role.

Adoption of specific measures under Regulation (EC) No 1935/2004 - relevant procedures and role of the European Parliament

Currently the adoption of specific measures under Article 5(1) of Regulation (EC) No 1935/2004 follows the so-called 'regulatory procedure with scrutiny'[11] (RPS). After the entry into force of the Lisbon Treaty on 1 December 2009, this regulation was scheduled for alignment to the 'delegated acts' procedure under Article 290 TFEU. However, in March 2015 the Commission withdrew its 2013 Lisbon-alignment proposals, arguing that the question 'will be addressed in the new interinstitutional agreement (IIA) on Better Regulation'[12]. As a result, under the new Better Regulation IIA approved in March 2016, the Commission undertook to table (by the end of 2016) new proposals for replacement of the RPS – which is still envisaged in many legal ('basic') acts for adoption of specific measures, including the FCM framework Regulation - by the system of delegated acts. This switch would give the European

[10] The 17 food contact materials/articles listed in Annex I to framework Regulation (EC) No 1935/2004 are: active and intelligent materials and articles, adhesives, ceramics, cork, rubbers, glass, ion-exchange resins, metals and alloys, paper and board, plastics, printing inks, regenerated cellulose, silicones, textiles, varnishes and coatings, waxes and wood.
[11] As defined in Article 5a of Council Decision 1999/468/EC (as amended in 2006).
[12] See withdrawal no. 55, p 11, Annex II to the Commission Communication on the 2015 Work Programme.

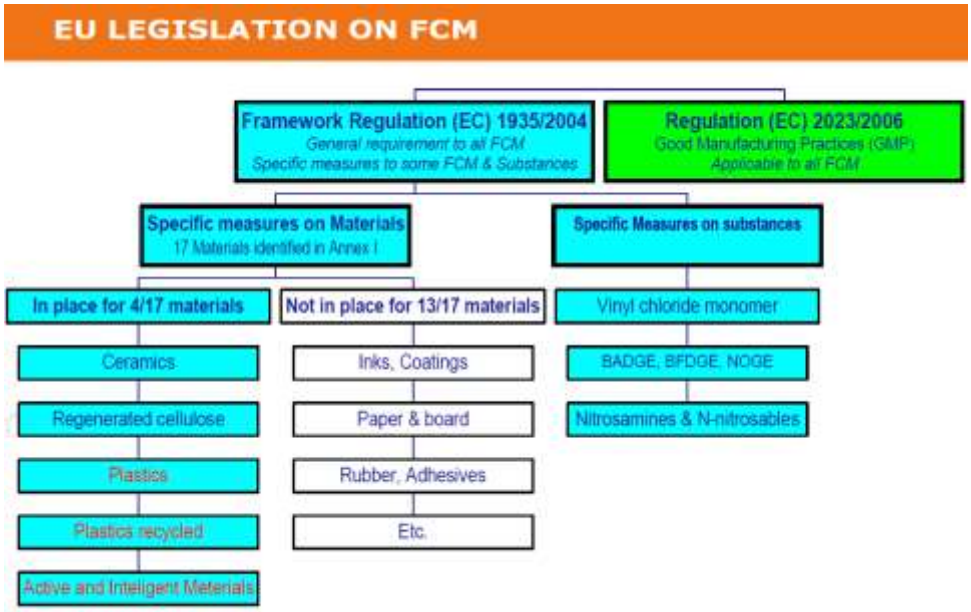
Parliament access to information during the preparatory drafting phase of delegated acts as also agreed in the framework of the recently adopted Better Regulation IIA[13].

So far, specific measures have been adopted for only four out of the seventeen food contact materials and articles listed in Annex I to Regulation (EC) No 1935/2004: active and intelligent materials, ceramics, regenerated cellulose film and plastics (including recycled plastics).

In addition, specific measures have been adopted for individual substances used in food contact materials.

The entire set of EU legal acts currently regulating the manufacture, processing and distribution of food contact materials is presented in Figure 1.

Figure 1: EU legislation on food contact materials



Source: EFSA

In the absence of specific measures adopted at EU level, the Member States are allowed to adopt such measures at national level provided they comply with the rules of the Treaty[14]. Several Member States have adopted national rules for some materials/articles listed in Annex I to the framework Regulation which were last mapped by the European Commission in 2014.

These national rules might vary from one Member State to another. For example: a substance might be forbidden in one Member State, authorised under certain limits and conditions in another, or not be regulated at all in a third one. Differences in technical rules imply the application of the principle of *mutual recognition*, according to which any

[13] See more details in the recent Briefing 'Interinstitutional Agreement on Better Law-Making'.
[14] See more details as regards FCM legislation adopted at Member States' level in Rijk R., R. Veraart 'Global legislation for food packaging materials', 2010.

product which is lawfully produced and marketed in one Member State, must, in principle, be allowed for marketing in any other EU Member State. However, Member States can suspend the marketing of the product for reasons related to safety and health of the users.

Although not legal 'implementing acts'[15], EU specific measures are implementing measures by nature, and therefore the existence or absence of specific measures for the relevant food contact materials has direct impact on the implementation of the framework regulation. The Joint Research Centre of the European Commission has conducted a base-line study aimed at providing a comprehensive description of the current situation concerning food contact materials for which there are no specific measures at EU level[16]. The Commission's evaluation of the final report of the JRC study is ongoing.

Authorisation of substances

When a list of substances authorised for use in the manufacturing of materials and articles exists[17], business operators seeking an authorisation for a substance not yet included in that list must submit an application for authorisation of this substance.

The authorisation procedure is laid down in Article 9 and following of framework Regulation (EC) No 1935/2004. Authorisations are given by the European Commission (also in the form of specific measures) after a mandatory opinion of the European Food Safety Authority (EFSA) which makes a risk safety assessment[18] of the relevant substance.

EU level authorisation of substances used in FCMs and the role of EFSA

The applicant business operator first submits its application for authorisation of substances to the relevant national competent authority which then informs EFSA for the application and transfers to it all relevant information. The application documentation consists of information regarding the applicant and the so-called 'technical dossier'. The dedicated Guidelines for the preparation and submission of applications - adopted in 2001 by EFSA's predecessor the Scientific Committee on Food[19] - contain detailed information about each step of the application procedure

[15] Under Regulation (EU) No 182/2011.
[16] See description of the scope and main research tasks of the study.
[17] As adopted under Article 5 (1)(a) and/or (b) of Regulation (EC) No 1935/2004.
[18] As defined in Article 3 of the General EU Food Law Regulation (EC) No 178/2002.
[19] Article 9(2) of Regulation (EC) No 1935/2004 stipulates that EFSA 'shall publish detailed guidelines concerning the preparation and the submission of the application'. In fact, EFSA, which was established in 2002 with the General Food Law Regulation (EC) No 178/2002, has not adopted such Guidelines yet, as required by Article 9(2). Thus applicants continue to follow the Guidelines adopted in 2001 by the Scientific Committee on Food. However, in January 2016, EFSA issued an opinion recommending the revision of the 2001 Guidelines. In particular, EFSA's experts recommend 'refining of the safety assessment of substances used in FCM, including the introduction of a more comprehensive approach to estimate consumer exposure, particularly for infants and toddlers'. Before adoption, the draft opinion was shared with Member States (Food Ingredients and Packaging (FIP) network on food contact materials) and underwent public

and the information that should be submitted by the applicant in the technical dossier.

As a general rule, EFSA has six months to issue its opinion as to whether, under the intended conditions of use of the material or article in which it is used, the substance complies with the general safety requirements of the framework Regulation[20]. EFSA could request supplementary information from the applicant which suspends the six-month deadline. If EFSA is in favour of authorising the evaluated substance, its opinion should include:

- the designation of the substance including specifications;
- where appropriate, recommendations for any conditions or restrictions of use for the evaluated substance and /or article in which it is used;
- an assessment as to whether the analytical method proposed is appropriate for the intended control purposes.

Based on EFSA's data, from 2004 until the end of 2015 the Authority has evaluated 348 substances.

As mentioned above, authorisations take the form of specific measures adopted by the European Commission. The draft specific measure should take into account EFSA's opinion, as well as other factors defined in Article 11(2) of the framework Regulation. Where the draft specific measure is not in accordance with EFSA's opinion, the Commission shall provide explanation for the difference. If the Commission does not intend to prepare a draft specific measure after a favourable opinion of EFSA, it shall inform the applicant and provide explanation for the refusal to grant authorisation.

No substance shall be authorised unless it has been adequately and sufficiently demonstrated that, when used under the conditions to be set in the specific measures, the final material or article satisfies the general safety requirement established in the framework Regulation, i.e. that the substance is stable enough so as not to migrate into the food in quantities that would endanger human health, or bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic characteristics.

Once granted an authorisation, the substance can be used only subject to the conditions or restrictions attached to the specific measure. Business operators using the authorised substance are obliged to immediately inform the Commission of any new scientific or technical information, which might affect the safety assessment of this substance in relation to human health. If necessary, EFSA reviews the risk assessment. Modifications, suspensions and revocations of authorised substances are also possible under certain conditions defined in Article 12 of the framework Regulation.

The authorisation procedure at EU level applies only to substances used in the food contact materials for which specific measures under Article 5(1) (a) and/or (b) of the framework Regulation have been adopted, i.e. 'lists of substances authorised for use in the manufacturing of materials and articles'. For the other FCMs (listed in Annex I to the

consultation. Upon relevant feedback from the European Commission, EFSA may start preparing new Guidelines to reflect its recommendations, as detailed in Part 4 of the study.

[20] In particular, Article 3 thereof.

framework Regulation) for which such specific measures have not been adopted, the relevant authorisation procedures (if any) established at Member States level apply.

Applications for EU level authorisation and all relevant information from applicants as well as the opinions of EFSA, excluding confidential information[21], are to be made accessible to the public subject to the relevant conditions laid in the EU General Food Law Regulation (EC) No 178/2002[22].

1.1.5. Labelling

The framework Regulation lays down rules as regards the labelling of food contact materials and articles not yet in contact with food and when placed on the market. In particular, the food contact materials in question should be accompanied by:

- the words 'for food contact', or a specific indication as to their use, such as coffee machine, wine bottle, soup spoon, or the symbol reproduced in Annex II to framework Regulation (EC) No 1935/2004 () [23], and
- if necessary, special instructions to be observed for safe and appropriate use, and
- the (trade) name and registered office of the manufacturer, processor, or seller responsible for placing on the internal market, and
- adequate labelling or identification to ensure traceability of the material or article, etc.[24]

The required information should be conspicuous, clearly legible and inedible. Within its own territory, the Member State in which the material or article is marketed may stipulate that those labelling particulars should be given in one or more languages which it shall determine from among the official languages of the EU. The framework Regulation lays down specific requirements for displaying the necessary information in each marketing stage, including the retail stage. The above requirements apply to all food contact materials and articles.

The labelling requirements play an important role in terms of traceability of food contact materials and articles.

1.1.6. Traceability of food contact materials and articles and relevant compliance documentation (declarations of compliance)

Traceability is an important element of the implementation of current EU FCM rules and, thus, directly impacts both the effective functioning of the internal market and FCM safety. The relevant requirements are laid down in Article 17 of framework Regulation

[21] Applicants for authorisations of substances may indicate which information in their application is to be considered as confidential. However, this opportunity is subject to certain conditions as regards information which could not be considered as confidential. The relevant rules are laid down in Article 20 of framework Regulation (EC) No 1935/2004.
[22] In particular, Articles 38, 39 and 40 thereof.
[23] This requirement is not obligatory for the articles, which are clearly intended to come into contact with food.
[24] Article 15 (1)(e) lays down specific requirements for active and intelligent materials.

(EC) No 1935/2004. In particular, the traceability of FCMs should be ensured at all steps in the supply chain in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility. This requirement is applicable to both harmonised and non-harmonised FCMs.

Business operators are obliged to have in place systems and procedures to allow identification of the businesses from which and to which materials and articles (including substances) are supplied. This information should be made available to the competent authorities.

The materials and articles which are placed on the market in the Community should be identifiable by an appropriate system which allows their traceability by means of labelling or relevant documentation or information.

Furthermore, to testify compliance, food contact materials for which specific measures at EU level exist, should be accompanied by the so called 'declaration of compliance'. This written document should state that the relevant food contact material(s) and article(s) comply with the rules applicable to them. The declared compliance should be demonstrated by appropriate documentation which should be made available to the competent authorities on their demand.

In the absence of EU specific measures for some food contact materials and articles, Member States may adopt national provisions for declarations of compliance.

Traceability and compliance documentation are key prerequisites for effective enforcement of the EU FCM rules.

1.1.7. Inspections, control measures and sanctions

Framework Regulation (EC) No 1935/2004 contains provisions on official controls that Member States should carry out to enforce compliance with its provision. Enforcement activities should be performed in accordance with relevant provisions of EU law relating to official food and feed controls, such as Regulation (EC) No 882/2004 on food and feed controls.

Where necessary and on the request of the Commission, EFSA should assist in developing technical guidance on sampling and testing to facilitate a coordinated approach for the application of relevant control requirements.

The EU Reference Laboratory on Food Contact Materials (EU-RL FCM) and the National Reference Laboratories (NRLs) [25] should assist Member States in their control activities by contributing to a high quality and uniformity of analytical results.

[25] The EU Reference Laboratory on food contact materials and the National Reference Laboratories are established by the Food and Feed Controls Regulation (EC) No 882/2004.
The EU Reference Laboratory for food contact materials is part of the Joint Research Centre of the European Commission. As for other EU Reference Laboratories, the EU-RL on food contact materials aims to ensure high-quality and uniform testing in the EU and supports the activities of the Commission on risk management and risk assessment in the area of laboratory analysis. Among other tasks, the EU Reference Laboratory provides National Reference Laboratories with analytical methods, staff training, collaboration with competent laboratories in non-EU countries, etc.

Member States are also obliged to lay down rules on sanctions applicable to infringements of the provisions of the framework regulation and shall take all measures necessary to ensure that they are implemented. The sanctions must be effective, proportionate and dissuasive.

1.1.8. Safeguard measures

The framework regulation creates an opportunity for individual Member States to temporarily suspend or restrict the application of certain provisions (including existing specific measures at EU level). This might be the case when a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for concluding that the use of a material or article endangers human health, even though the material/article formally complies with the relevant general or specific requirements.

In such cases the Member State in question should immediately inform the European Commission and the other Member States and give reasons for the suspension/restriction. The Commission would then, after obtaining the opinion of EFSA, examine[26] the grounds of the Member State and deliver an opinion without delay and take appropriate measures. The Commission may also consider adopting amendments to the relevant specific measures. The Member State applying the safeguard measure may retain the suspension or restriction until the amendments to the relevant specific measure have been adopted or the Commission has declined to adopt such amendments.

1.2. Other sources of rules for food contact materials

Exports of EU-made FCM goods to third countries (such as China, Switzerland, USA, Canada, etc.), require compliance of EU business operators with the relevant rules governing the markets of these countries[27]. In addition, some businesses comply with third countries' FCM rules on a voluntary basis mostly to compensate the lack of specific measures adopted at EU and/or national (EU Member States') level for the FCM material/article that they market in the EU.

Furthermore, the Council of Europe (CoE) has developed a substantial set of non-binding rules (in the form of 'resolutions' and 'technical documents') that require transposition in national legal order to become binding. Currently, in the absence of specific measures adopted within the framework of the European Union, i.e. under Article 5(1) of framework Regulation (EC) No 1935/2004, several FCM industries comply (mostly on voluntary basis) with the rules established by the Council of Europe[28].

Finally, businesses often apply standards established at industry level, as a form of 'self-regulation' ('self-assessment'). However, as a general rule, industry 'self-regulation' is

[26] Within the 'Regulatory Procedure with Scrutiny' Committee which also participates in the adoption of specific measures under Article 5 (1) of the framework Regulation.
[27] For more details as regards third countries' legislation see in Rijk R., R. Veraart 'Global legislation for food packaging materials' (2010) as well as Barnes K. (et al.) 'Chemical migration and food contact materials' (2007) and Food safety policy and regulation in the United States, European Parliament Policy Department A, Economic & Scientific Policy, 2015.
[28] For more details, see Chapter 3 'Council of Europe resolutions' by Luigi Rossi in Rijk R., R. eraart 'Global legislation for food packaging materials', 2010.

committing only members willing to comply with it and does not constitute a legal basis for enforcement by competent authorities or commit importers of FCM goods.

2. Methodology

2.1. Data collection and processing

Data on the implementation of current EU FCM rules was collected via a questionnaire structured around closed and open-ended questions[29]. It was addressed to stakeholders via e-mail between December 2015 and February 2016.

The questionnaire was designed to collect information allowing for the assessment of implementation against the following set of 'key assessment criteria' for evaluations:

- **Relevance:** Is the intervention still relevant and do the original objectives still correspond to EU needs?
- **Coherence:** Is the intervention coherent with other comparable interventions, with itself and with the overall EU priorities?
- **European Added Value:** If there are effects/changes due to the intervention, could they have been equally or better achieved by the Member States themselves?
- **Effectiveness:** Have the objectives been achieved and are the effects/changes caused by the intervention?
- **Efficiency:** Are the costs and time/work spent for the effects/changes due to the intervention justified and proportionate?

These are internationally recognised criteria, adapted to an EU context. They are used to achieve a broad and coherent scrutinising perspective.

Two additional assessment criteria, pertinent specifically for the EU FCM policy, were also checked, namely:

- **Utility:** To what extent do the changes/effects of an intervention satisfy (or not) stakeholders' needs? How much does the degree of satisfaction differ according to the different stakeholder groups?
- **Complementarity:** To what extent do EU policies and interventions support and usefully supplement other policies (in particular those pursued by the Member States)?

The above assessment criteria were translated into specific questions covering the implementation of current EU FCM policy, and in particular framework Regulation (EC) No 1935/2004, which is the focus of the ENVI implementation report. Furthermore, the questionnaire was tailor-made to reflect the specific implementation roles of the stakeholders to whom it was addressed[30]. Several complementary questions were included in the relevant questionnaires aimed at taking stock of specific implementation activities. Annex I to this study presents all questions, the categories of stakeholders to whom they were addressed, as well as the assessment criterion/criteria that was/were checked with each question.

[29] See Annex I to the study.
[30] See further details on the stakeholders participating in the survey under 2.3 'Representativeness of the study', in this part of the study.

Stakeholders' responses are considered to be their official positions and/or that of the organisations representing their interests. Responses are up-to-date as per the time of their submission, i.e. between December 2015 and February 2016.

Some stakeholders sent additional documents (sector-specific guidelines, national pieces of legislation, recommendations to policy-makers, etc.), which were also considered as a source of empirical data.

Stakeholders provided responses with various degrees of exhaustiveness, accuracy and clarity. Wherever necessary, clarifications were asked, and information cross-referenced for validation.

The findings of this study are based exclusively on the data submitted by the stakeholders participating in the survey.

It should be borne in mind that the questionnaire only collects stakeholders' **perceptions of implementation**. This means that the view stakeholders are sharing may not necessarily reflect an actual fact.

Data processing involved categorisation of the information received (in response to open-ended questions), which allowed for comparison of the submitted replies to be made and thus trends, if any, to be outlined.

Some responses were irrelevant to the question under which they were submitted but relevant to other questions included in the questionnaire and were thus taken into account as pertinent answers with regard to the latter question.

Not all stakeholders made recommendations under the dedicated question[31]. However, in various parts of their responses they expressed ideas for action which were taken into account in data processing.

Dedicated questions aimed at assessing the implications for SMEs of the implementation of the current EU FCM rules were included in the relevant questionnaires. However, these were largely left unanswered, mainly because stakeholders did not have available data. Therefore, it was impossible for trends to be outlined as regards SMEs manufacturing, processing or distributing FCMs.

[31] 'If you consider it important, please comment on issues which couldn't be raised answering the above questions and also express your recommendations for improvement of current EU FCM rules and their implementation?'

2.2. Identification and selection of relevant stakeholders

2.2.1. Identification of relevant stakeholders

Relevant stakeholders were identified based on their role (legally binding obligations) in the implementation of current EU FCM rules as well as their legitimate interest in the achievement of the relevant market and safety objectives laid down in framework Regulation (EC) No 1935/2004.

Thus, the following categories of stakeholders were identified:

Stakeholders with legal obligations under Regulation (EC) No 1935/2004

- Businesses, i.e. the manufacturers, processors and distributors of food contact materials;
- Competent Authorities of the EU Member States;
- European Commission's relevant services: DG SANTE, including its Directorate Health and Food Audit and Analysis (FVO)[32], the EU Reference Laboratory on Food Contact Materials (EU-RL FCM)[33], and,
- European Food Safety Authority.

Stakeholders without legal obligations under Regulation (EC) No 1935/2004 but having legitimate interest in the achievement of its market and safety objectives

- Consumers stakeholders;
- Health stakeholders;
- Environment stakeholders;
- Businesses directly using FCM products.

In addition, the FCM scientific community (including individual researchers) was also addressed with a questionnaire aimed at identifying key research challenges in the field of food contact materials.

2.2.2. Selection of relevant stakeholders

In total, 91 individual stakeholders among the above categories were invited to fill in a tailor-made questionnaire aimed at collecting data on the implementation of the current EU FCM rules.

2.2.2.1. Selection of stakeholders with legal obligations under Regulation (EC) No 1935/2004

While institutional stakeholders – European Commission, EFSA, Member States' competent authorities – were selected by default[34], businesses, which as a general rule are represented at EU level by a number of dedicated organisations, had to be identified on

[32] Mostly known as 'Food and Veterinary Office'.
[33] The EU-RL FCM is part of the Joint Research Center of the European Commission.
[34] As specifically named by framework Regulation (EC) No 1935/2004.

the basis of additional selection criteria in order to make this survey possible within the ENVI Committee's agenda timeframe.

Thus, the focus of selection was put on the **manufacturers** of the food contact materials, and, wherever possible, and based on the market share of the relevant food contact material, also on the **processors** of this material/article. Wherever two or more EU level business organisations were found to represent, for example, the manufacturers of one and the same food contact material, only the most representative one[35] was addressed with a questionnaire.

At least one business organisation representing at EU level the **manufacturers** of each of the seventeen food contact materials[36] was invited. At least one business organisation representing at EU level the **processors** of plastics, paper & board, metals & alloys, and glass was also invited. **Distributors** of individual food contact materials and articles were difficult to identify and, therefore, one organisation representing at EU level whole-sale and retail trade was invited to fill in a questionnaire on behalf of FCM distributors.

2.2.2.2. Selection of stakeholders with legitimate interest in the achievement of the market and safety objectives of Regulation (EC) No 1935/2004

As mentioned above, four categories of stakeholders with legitimate interest in the achievement of market and safety objectives were identified. Stakeholders under these four categories were selected based on thorough research of their activities in the field of food safety, and food contact materials in particular. Several organisations were invited so that diversification of opinions could be ensured.

Researchers were selected based on their proven expertise in the field of food contact materials. Several research organisations and individual researchers were invited, so that diversification of opinions could be ensured.

2.3. Representativeness of relevant stakeholders

In total, 61 of all 91 individual stakeholders who were invited to take part in the survey, responded to the relevant questions. See Graph 1 below.

However, there were some cases in which stakeholders (normally, umbrella organisations) did not have expertise to fill in the questionnaire[37], declined to do so or did not reply to the invitation. In order to respect confidentiality in such cases, Annex II to

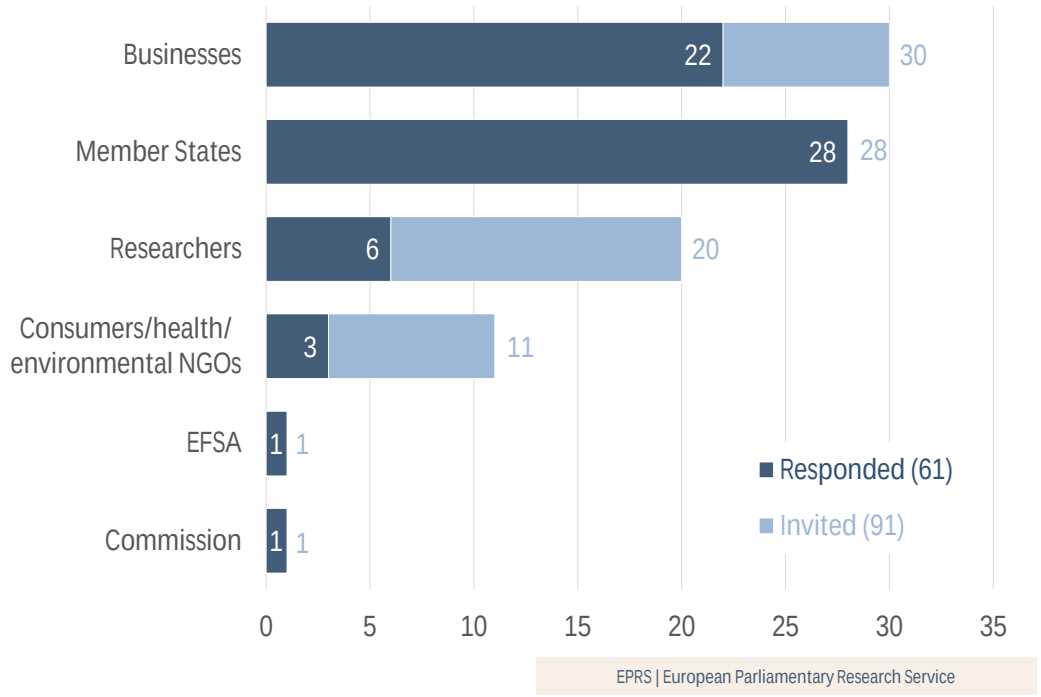
[35] That is, the stakeholder organisation with the largest membership in terms of both individual companies and national associations covering the biggest number of EU Member States, and possibly EU trade partner countries.

[36] Listed in Annex I to framework Regulation (EC) No 1935/2004.

[37] There were cases where the EU umbrella organisation contacted did not have expertise to respond and thus the questionnaire was forwarded to a dedicated member organisation possessing expertise. As a general rule, in such cases, the submitted responses speak for this dedicated member and not for the EU umbrella organisation. For details see Annex II to this study.

this study lists only the names of stakeholders who did take part in the survey by filling in a questionnaire.

Graph 1 Stakeholders participating in the survey*



* the category of businesses here includes: businesses (manufacturers and/or processors), businesses (distributors) and businesses (directly using FCM products).

2.3.1. Representativeness of the stakeholders with legal obligations under Regulation (EC) No 1935/2004

All categories of stakeholders with legal obligations under Regulation (EC) No 1935/2004 – businesses, EFSA, the relevant services of the European Commission and the competent authorities of all 28 EU Member States – took part in the survey.

Businesses' representativeness

In total, 19 organisations of manufacturers[38] and processors[39] of food contact materials listed in Annex I to Regulation (EC) No 1935/2004 responded, thus speaking for thirteen

[38] These manufacturers' organisations cover the following 13 food contact materials listed in Annex I to Regulation (EC) No 1935/2004: ceramics, plastics, paper & board, printing inks, glass, metals & alloys, coatings (and can coatings in particular), cork, rubbers, silicones, adhesives, wood, waxes. See Annex II to this study for details.

[39] These processors' organisations cover the following three food contact materials: glass, metals & alloys, and paper & board. In addition, two spontaneous requests for participation in the survey were submitted by organisations representing the processors of glass and steel for packaging. The requests were admitted.

(out of the seventeen) FCMs listed in this Annex: ceramics, plastics, paper & board, printing inks, glass, metals & alloys, coatings (and can coatings in particular), cork, rubbers, silicones, adhesives, wood, waxes[40]. The manufacturers of additives also took part in the survey[41] and thus the total number of **businesses (manufacturers and/or processors)** is 20.

One organisation representing wholesale and retail trade took part in the survey representing **businesses (distributors)**.

Although **businesses (directly using FCM products)** do not, strictly speaking, fall into the category of 'stakeholders with legal obligations under Regulation (EC) No 1935/2004', they are generally considered as 'businesses' together with 'businesses (manufacturers and/or processors)' and 'businesses (distributors)'[42]. One organisation representing businesses directly using FCM products took part in the survey.

Thus, the total number of 'businesses' participating in the survey is 22 out of the 30 business stakeholders' organisations that were invited.

The questionnaire that was sent to the selected business organisations contained questions aimed at identifying their representativeness. However, these questions were unequally addressed by business stakeholders and thus uniform identification via common criteria was not possible. Furthermore, as mentioned above, some umbrella organisations forwarded the questionnaire to their dedicated member(s). Thus, the representativeness of businesses (as regards compliance aspects of the EU FCM rules) is specific in each individual case and could not be strictly determined. The data submitted by business organisations under this survey speaks only for the members that they represent[43].

National competent authorities' representativeness

All 28 Member States took part in the survey via their dedicated national food safety authorities and/or their Permanent Representations to the EU, thus accounting for 100 % representativeness of the study as regards enforcement aspects of the EU FCM rules at national level[44].

In fact, several of the business stakeholders, selected and addressed to represent 'processors' of the relevant FCM, defined themselves as 'manufacturers' of this material. Therefore a clear distinction between 'manufacturers' and 'processors' could not be established. Hereafter, therefore, these two are considered together as 'businesses (manufacturers and/or processors)'. See Annex II to this study for more details.

[40] The four food contact materials that are not covered by this survey are: active and intelligent materials, regenerated cellulose film, ion exchange resins, and textiles.

[41] Manufacturers of additives, which are not listed in Annex I to the framework Regulation but largely used in the manufacture and processing of some food contact materials and articles, sent a spontaneous request to participate in the survey, which was granted. See Annex II.

[42] Thus, wherever this study refers to 'businesses', this means the organisations representing the following three categories of business stakeholders: businesses (manufacturers and/or processors), businesses (distributors) and businesses (using FCM products directly). See Annex II. Wherever necessary, distinctions between the three categories of businesses are made.

[43] See Annex II for more information as regards business organisations' representativeness and membership.

[44] Wherever this study refers to 'Member States', this means the competent authorities of the Member States under Regulation (EC) No 1935/2004. See Annex II.

2.3.2. Representativeness of stakeholders with legitimate interest in the achievement of the market and safety objectives laid down in Regulation (EC) No 1935/2004

Three out of the eleven organisations invited to speak for consumer, health and environmental aspects of the implementation of current FCM rules submitted responses.

Consumers' representativeness

In total, two consumer organisations took part in the survey[45].

Health and environmental stakeholders' representativeness

Health and environmental aspects of the implementation of current EU FCM rules were only assessed by one organisation which filled in a dedicated questionnaire[46].

The data submitted by consumer, health and environmental organisations under this survey speaks only for the members that they represent[47].

The participation of researchers in the survey remained low. As a result, one research organisation and five[48] individual researchers took part in the survey[49] out of the 20 research stakeholders that were invited.

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* *

The above representativeness data shows that this survey is far more representative as regards stakeholders with legally binding implementation obligations under framework Regulation (EC) No 1935/2004 - and in particular businesses and national competent authorities - than it is with regard to stakeholders with legitimate interest in the achievement of its market and safety objectives.

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[45] Wherever this study refers to 'consumers', this refers to the two organisations representing consumers that submitted responses under this survey. See Annex II.

[46] Wherever this study refers to 'health/environmental NGOs', it means the sole organisation representing health and environmental aspects of EU FCM policy that took part in this survey. See Annex II.

[47] For more details regarding consumer, health and environmental organisations' representativeness and membership, see Annex II.

[48] This number includes the sole spontaneous request (submitted by an individual researcher) to participate in the survey that was received and admitted. See Annex II.

[49] For the sake of confidentiality, the names of individual researchers who submitted responses are not disclosed. Wherever this study refers to 'researchers', this signifies the answers of the six stakeholders speaking for FCM research aspects (i.e. one organisation and five individual researchers who submitted responses under this survey).

3. Key findings: stakeholders' perception and assessment of 'food contact materials' implementation reality[50]

3.1. Assessment of current EU FCM rules

3.1.1. Assessment of the current EU FCM policy objectives and instruments (checking Relevance and Coherence)

Q 1: (addressed to businesses[51], competent authorities, Commission, EFSA, consumers[52], health/environmental NGOs[53], researchers)

From your perspective, do the original objectives, laid down in framework Regulation 1935/2004, still correspond to real needs?

Please reply by 'yes' or 'no'.

If you have replied by 'no', please briefly describe what the objectives should be from your perspective?

Almost all stakeholders have indicated an answer under this question.

A large majority of respondents (across all categories of stakeholders) considers that the objectives laid down in framework Regulation (EC) No 1935/2004 still correspond to real needs. Even from the very few 'no' answers it is clear that the arguments refer far more to the relevance of current EU FCM rules to the original objectives, and hence, these responses were taken into account under Q 2.

No stakeholder has suggested new objectives that should be incorporated in the EU FCM policy.

[50] The qualifiers used in this part of the study should be interpreted in the following order of magnitude:

- Individual: 0 to 10 % or responses
- Some: 10-25 % of responses
- Several: 25-50 % of responses
- Half: 50 % of responses
- Majority: 50 % of responses + one response
- Large majority: more than 75 % of responses

[51] See Annex I for details of which question was put to which of the three 'business stakeholders' categories – businesses (manufacturers and/or processors), businesses (distributors) and businesses (directly using FCM products). As the categories of businesses (distributors) and businesses (directly using FCM products) are represented by only one organisation each, wherever relevant, their responses are quoted individually.

[52] Consumer stakeholders are represented by two organisations – one national consumer organisation (i.e. Member State-specific) and one umbrella EU organisation. Therefore, wherever relevant, their responses are quoted individually.

[53] Health/environmental stakeholders are represented by one organisation only, and therefore, wherever relevant, its responses are quoted individually.

Conclusion: the original objectives, as laid down in framework Regulation (EC) No 1935/2004, are still relevant to stakeholders' real needs. Respondents do not consider the incorporation of new objectives necessary.

Q 2: (addressed to businesses, competent authorities, Commission, EFSA, consumers, health/environmental NGOs, researchers)

From your perspective, are current EU FCM rules still relevant to the original objectives? Please reply by 'yes' or 'no'.

If you have replied by 'no', please briefly describe why?

Almost all respondents have indicated an answer under this question.

The majority of stakeholders (across almost all categories) consider that the current EU FCM rules are still relevant to the original objectives laid down in the framework Regulation (EC) No 1935/2004. However, the rate of 'yes'/'no' answers differs among the different categories of stakeholders. Furthermore, the majority of both 'yes' and 'no' opinions are accompanied by comments (summarised below).

Businesses (manufacturers and / or processors)

The majority of business stakeholders consider that the current EU FCM rules are relevant to the original objectives. However, the rate of 'no' answers is also significant.

Both 'yes' and 'no' answers are accompanied by comments. More than the half of the businesses participating in the survey consider that, although relevant to real needs, the current EU FCM rules are not 'complete/sufficient/clear' and that the lack of EU specific measures for some FCMs pose problems for the achievement of the original objectives.

Businesses (distributors)

EuroCommerce:
'Yes, the regulation still responds to our expectations. Nevertheless, based on the new EFSA opinions, some updates are needed. Regarding emerging substances, imposing thresholds/limits at the level of the individual Member States can create complex situation in the B-to-B supply chain and fragmentation of the single market in the EU. Examples are the contamination by mineral oil hydrocarbons and the BPA measures.'

Businesses (directly using FCM products)

FoodDrinkEurope
'Yes it is still relevant but specific measures have only been adopted for a very limited number of materials, compared to the list of materials that may be subject to a specific measure as established in Annex I to Regulation 1935/2004. This leads to a strong heterogeneity in the regulation for harmonised and non-harmonised materials. For non-harmonised materials this leaves room for interpretation of the rules by individual players, and the establishment of various national rules by MS. For non-harmonised materials, the fact that some MS have legislation and some do not suggests that various safety standards are applied between different MS, which generates mistrust from consumers. Mutual recognition does not always work well. Eventually, even for some

harmonised materials, local rules can be adopted and distort the functioning of the internal market (i.e.: BPA national bans which go further than the EU rule).'

Competent authorities

Almost all Member States participating in the survey have replied positively to this question. As with businesses, several competent authorities have indicated that, although relevant to real needs, the current EU FCM rules are not 'complete/sufficient/clear/up-dated' and that the lack of specific measures at EU level for some FCMs pose problems for the achievement of the original objectives.

European Commission: n/a

The lack of answer should be interpreted in the light of the answer indicated by the Commission under Q 9:

> 'As you are aware, Regulation (EC) No 1935/2004 empowers the Commission to adopt and amend specific measures on special food contact materials and articles. However, only for certain materials, notably plastic materials, specific measures have been introduced at EU level. In order to prioritise the risk management of FCMs, decisions to progress and adopt further specific measures are based on available information and evidence about the risk to consumer health as well as the internal market and take account of the principles of subsidiarity and proportionality. This is done in a structured manner in applying the Commission better regulation principles[54]'.

EFSA has indicated the following answer:

> 'The rules are relevant, and it is important that they are applied in a consistent and comprehensive manner to ensure the safety of all food contact materials. When rules are in place, especially for plastics, the almost exclusive focus on only starting substances misses the many other classes of substances (used or produced during manufacturing of FCM) that migrate into foods'.

Consumers

Consumer organisations unanimously consider[55] that the current EU FCM rules are not relevant to the original objectives laid down in framework Regulation (EC) No 1935/2004 and put forward as a main reason the lack of specific measures adopted at EU level for the majority of FCMs listed in Annex I to the framework Regulation.

ANEC:

> 'Specific rules are outdated or missing for many materials (see answer to Q 7[56]).
> Only plastics materials are comprehensively regulated (although there are still significant gaps), furthermore only a small group of other materials such as

[54] See in particular Commission Staff Working document Better Regulation Guidelines (SWD(2015) 111 final), p. 23.

[55] DCC has not formally replied to this question, but made other general comments at the beginning of their questionnaire, which were taken into account.

[56] That is, Q 15 in Part 3 of the study.

elastomers/rubbers and ceramics are covered to some extent (though anything else than adequate). Non-intentionally added substances (NIAS) are of big concern but are covered only in a generic fashion. Nanomaterials are regulated, but only when it comes to plastic materials, where it explicitly is stated that nanomaterials are only to be used when they are on an authorisation list.'

Health/Environmental NGOs, represented by ChemTrust, stick to consumers' position, stating that:

'The lack of harmonised regulations on chemicals in many food contact materials means that there is not a high level of protection of human health and the interests of consumers. In addition, the continued use of SVHC chemicals in harmonised materials is not consistent with this aim'.

Researchers also tend to consider that the current EU FCM rules are not relevant to the original objectives because of lack of specific measures adopted at EU level for the majority of FCMs listed in Annex I to the framework Regulation. Furthermore, researchers indicate that an up-date of existing rules is also necessary to reflect scientific reality.

Conclusion: although the majority of stakeholders, participating in the survey, formally consider the current EU FCM rules as relevant to the original objectives, several stakeholders (across most categories of stakeholders) also considers that the current EU FCM rules are not sufficient to ensure the achievement of the original objectives, especially as far as non-harmonised FCMs are concerned. In particular, the adoption of specific measures at EU level for the FCMs listed in Annex I to Regulation (EC) No 1935/2004 (and currently not covered by such specific measures) is a common recommendation.

Q 3: (addressed to businesses, competent authorities, Commission, EFSA, consumers, health/environmental NGOs)

From your perspective, are there other possible policy instruments/measures at EU level (besides legal regulation) that would also support the achievement of the original objectives or of the objectives you have suggested above?

Please reply by 'yes' or 'no'.

If you have replied by 'yes', please briefly describe the instrument/s and its/their relevance to the original and newly suggested objectives?

The majority of stakeholders have indicated an answer under this question.

As a general trend, respondents are in favour of policy instruments complementary to the current legislative instruments in force. However, among those supporting additional (non-legislative) policy instruments, there are policy options which are legal by nature, and very often refer to the need of specific measures at EU level for the FCMs that are currently not covered by such measures. Voices in favour of legal regulation as sole policy instrument are also numerous.

Businesses (manufacturers and/or processors)

The large majority of businesses participating in the survey are in favour of legal regulation supplemented by non-legal policy measures (legal regulation being reconfirmed as the most desired policy option by the majority of businesses participating in the survey).

The following non-legal policy options are mentioned by businesses (listed in order of preference):

- industry self-regulation/industry self-assessment - listed by nearly half of businesses participating in the survey;

- guidance/guidelines - level of adoption is specified (e.g.: Commission guidance/European level guidelines or guidance at industry level/which could mean industry self-regulation/); however, the purpose and nature of the guidance instrument could not be clearly outlined; this non-legal policy instrument is listed only by individual businesses;

- mutual recognition principle (in particular, mechanisms to make it work properly among EU Member States are needed but also acceptance of approvals given outside Europe and that follow equivalent scientific principles aimed at ensuring safe use/e.g. USA/) - listed only by individual businesses;

- Council of Europe resolutions/statements - having the potential to serve as a basis for FCMs currently not covered by specific measures - answer indicated by some businesses.

Businesses (distributors)

EuroCommerce:
'Yes, some sectors have implemented voluntary declaration of conformity (for food contact material – Guide ANIA – CLIFE on the template). For example in France, the DGCCRF is publishing, in collaboration with Business Organisations, fact sheets on FCM to help business to comply with the law. In addition, individual companies conduct testing, awareness raising and compliance control as part of their integral quality systems.'

Businesses (directly using FCM products)

FoodDrinkEurope:
'Yes. To achieve these goals standards and technical guidelines can be used, such as industry's guidance document on paper & board, EUPIA guidelines, etc. FoodDrinkEurope would welcome the endorsement of the guidelines by the Standing Committee on Plants, Animals, Food and Feed. Additionally, these goals can be achieved through the Council of Europe. Industry would welcome being associated in their work. In this case this would remain an interesting platform to produce guidelines or resolutions that can be good references for some materials. We welcome the harmonisation on FCM legislation but it should be simpler than the plastic Regulation.'

Competent authorities

Member States are equally divided in their answers under this question: half of them consider that legal regulation is the only policy instrument that should be used in the field of FCMs, while the other half considers that next to legal regulation other policy instruments might be useful. The non-legal policy instruments quoted most often are:

- guidance/guidelines - level of adoption is not always specified (wherever specified though, it is clearly positioned at EU level, some MS have also indicated that the guidance approach established for plastics should be followed) - listed by the majority of Member States opting for additional non-legal instruments;

- coordination between competent authorities at EU level, such as exchange of best practices of enforcement, joint inspections (also at EU level), EU monitoring programme, EU database for national requirements, cooperation between EFSA and MS are mentioned by individual Member States;

- training for competent authorities/businesses/consumers - also listed by individual Member States.

European Commission:

'Besides regulatory measures the European Commission also considers in this context alternative instruments, such as strengthening industry self-regulation or mutual recognition.

Accordingly, and taking into account the interests of stakeholders including EU Member States, industry organisations and consumers, DG SANTE has tasked the JCR to carry out a 'base-line' study in order to provide a comprehensive description of the current situation concerning food contact materials for which there are no specific measures at EU level. The study will allow the European Commission to assess what, if any, possible steps need to be taken in the future concerning the regulation of FCMs.

It should be noted that a number of other initiatives are also being carried out within the European Commission which are relevant to the area of food contact materials. This includes the fitness check on general food law, the single market strategy which, among others, aims to improve the application of mutual recognition, as well as the on-going REACH[57] evaluation and the fitness check on chemicals legislation including food contact materials and how to maximise the use of existing legislation and/or data'.

EFSA suggests the following policy instruments (besides legal regulation):

'Harmonised methodologies for safety assessment; cooperation between MS and EFSA'.

Consumers (ANEC) and **health/environmental NGOs** tend to consider that legal regulation should be the preferred policy instrument.

[57] The so-called 'REACH' Regulation (EC) No 1907/2006, establishing EU policy on chemicals.

An opinion expressed by a **researcher** (under another question) also indicated that guidelines for risk assessment are necessary. However, the level at which these guidelines should be adopted is not specified.

Conclusion: Non-legal policy instruments are generally acceptable for stakeholders, especially as far as businesses and competent authorities are concerned. Consumer and health/environmental NGOs insist on legal regulation. Besides regulatory measures, the European Commission also considers in this context alternative instruments, such as strengthening industry self-regulation or mutual recognition. While guidance documents (presumably at EU level) emerge as the preferred non-legal policy instrument, especially for businesses and competent authorities, their purpose and target are difficult to be clearly outlined. Reading the responses of stakeholders in the light of the information submitted under other questions, one could assume that guidance at EU level is necessary to clarify how legal requirements are to be applied in practice so that uniform compliance and enforcement (for both FCMs covered and not covered by EU specific measures) could be ensured.

3.1.2. Assessment of the scientific basis on which EU food contact materials rules are being adopted (checking Effectiveness/Utility)

Q 4 (addressed to businesses, competent authorities, Commission, EFSA, health/environmental NGOs, researchers)

> ***From your perspective, which are the articles and materials, and hence substances, that are studied sufficiently, and which are the articles and materials (hence substances) for which scientific knowledge (including analytical methods) still needs to be developed, so as to ensure that the adoption of 'specific measures' at EU and/or national level (including 'authorisations of substances') is based on 'adequate and sufficient' evidence?***

Almost all stakeholders have indicated an answer under this question. However, not all responses are pertinent to the question, but they are a minority. Among those who have specified the concrete FCM(s) (substances) as sufficiently or insufficiently studied, the following answers prevail:

Businesses (manufacturers and/or processors)

The majority of the businesses participating in the survey have indicated an answer pertinent to the question. They naturally tend to consider the FCM that they are manufacturing/processing as sufficiently (or at least well) studied so as to allow for adoption of specific measures at EU level, and refrain from assessing other FCMs.

Some businesses (but less than the majority of business stakeholders participating in the survey) have made comments on more than one FCM. These answers assess the FCM currently covered by EU specific measures as sufficiently studied.

NIASs are mentioned by individual businesses as requiring further research and development of appropriate analytical methods. Two paper processors' organisations

have made a comment which is worth mentioning in the general context of the observations made under this and other questions, in the sense that 'there might be some gaps (as regards studying paper & board) that would require additional evaluation (e.g. mineral oils)'.

Furthermore, businesses actively comment on analytical methods such as composition determination, migration testing and risk assessment. Under this and other questions some businesses (e.g. rubbers, paper & board, silicones, cork) report that, in the absence of EU specific measures, these materials are being tested (for migration) with methods developed for plastics which is considered inappropriate and misleading the test results. These businesses plead for material-specific analytical methods to be developed for FCMs which are currently not covered by EU specific measures.

Furthermore, analytical methods should to be standardised (harmonised) at EU level. According to the businesses providing this answer, this approach would allow for the same safety standard to be reached across Europe, and would avoid the current situation of different methodological models being applied by competent authorities, thus facilitating compliance.

Although not required to do so, under this question individual businesses have voiced support for EU specific measures for all or some of the FCMs listed in Annex I to Regulation (EC) No 1935/2004. Such specific measures might include, among others, the standardisation of analytical methods.

Competent authorities

Almost all competent authorities have indicated an answer to this question. The majority of answers are pertinent to the question.

FCMs currently covered by EU specific measures are considered by nearly half of the Member States to be sufficiently or, at least, more studied than non-covered ones (with plastics taking the lead), followed by ceramics mentioned only by individual Member States. Among FCMs not covered by EU specific measures glass is mentioned by individual Member States to be sufficiently studied. Although plastics are topping the rank, several competent authorities mention that studying NIASs in plastics (and NIASs in other FCMs) remains a challenge but also that research developments are constantly needed in this fast developing sector. Furthermore, two Member States mention Bisphenol A (BPA) as sufficiently studied but its substitutes (analogues BPF, BPS etc.) as requiring more scientific knowledge – an opinion also shared by some researchers (see below).

The FCMs most often mentioned by competent authorities as requiring more knowledge, so as to ensure that the adoption of 'specific measures' at EU and/or national level (including 'authorisations of substances') is based on 'adequate and sufficient' evidence, are (listed in order of preference):

- Paper & board (mentioned by 12 MS)
- Printing inks (mentioned by 11 MS)
- Silicones and coatings (mentioned by 9 MS each)
- Rubbers (mentioned by 8 MS)

Materials such as: metals & alloys, cork, wood, waxes, adhesives are only quoted by individual MS.

Like businesses, competent authorities also comment on challenges as regards analytical methods (such as composition determination, migration testing, risk assessment evaluation but also specific methods for control of compliance).

However, not all Member States have outlined a precise link between the FCMs and concrete scientific knowledge that is needed for the relevant material. A minority of MS who have drawn such a link tend to consider migration testing as the most important scientific knowledge necessary as regards especially paper & board, printing inks, silicones, coatings and rubbers.

Generally speaking, Member States are favourable to standardising analytical methods by harmonisation at EU level. Although not required to do so under this question (and like businesses), several MS have raised voices in favour of EU specific measures for non-harmonised FCMs.

European Commission - n/a

EFSA:

> 'From EFSA's perspective, existing scientific knowledge could help to support any possible evaluation of can coatings in a manner analogous to plastics at EU level. For other materials such as paper & boards, inks, rubber and elastomers, significant adaptation would be necessary. For those materials, some knowledge and expertise exist at national level. EFSA, MS and the Commission need to work together to make optimal use of both'.

Under this question, **health/environmental NGOs**, represented by ChemTrust, consider that:

> 'there need to be harmonised measures, including authorisations of substances, for all food contact materials'.

ChemTrust refers to NIASs as substances of unknown structure whose hazard effects are hard to assess. The organisation also comments on PFCs, Phthalates and Bisphenols, used in plastic and non-plastic FCMs, giving examples of studies detecting harmful health effects of these man-made chemicals.

No clear trend could be identified based on **researchers' responses**. The magnitude of researchers' opinions is very wide - ranging from '(strictly speaking) no FCM (substances) is/are sufficiently studied' to listing BPA as 'sufficiently studied' and stating that 'FCM research is not the bottleneck but the implementation of the general rules and the effectiveness of the present control by the authorities'. Paper & board, silicones, NIASs (in plastics) are isolated cases of FCMs (substances) quoted as insufficiently studied. Some recommendations are also made. Researchers also raise voices in favour of regulation of all FCMs which are currently not covered by EU specific measures.

Conclusion: Generally, stakeholders (across most categories) tend to consider that FCMs currently covered by specific measures (plastics in particular) are sufficiently (or at least more) studied than non-covered FCMs.

Almost all FCMs that are currently not covered by such measures, are indicated (mainly by competent authorities) as requiring more research so as to allow the adoption of such measures. NIASs are often quoted as a scientific challenge by several stakeholders across most of the categories to which this question was addressed.

Several stakeholders have voiced support for specific measures for all or some of the FCMs listed in Annex I to Regulation (EC) No 1935/2004. In particular, the harmonisation at EU level of analytical methods - such as composition determination, migration testing, risk assessment evaluation, but also specific methods for control of compliance - is recommended.

Q 5 (addressed to businesses, competent authorities, Commission, EFSA, consumers, health/environmental NGOs, researchers)

> ***In your opinion, are new developments in research sufficiently taken into account by EU and national policy-makers when setting up new FCM rules at EU and national level (including 'specific measures' for the articles and materials listed in Annex I to Regulation (EC) 1935/2004 and 'authorisations' of substances)?***
>
> ***Please, reply by 'yes' or 'on'. If you have replied by 'no', please briefly describe why.***

Almost all stakeholders have indicated an answer under this question. 'Yes' and 'no' answers are almost equal in numbers.

The only trend that could be clearly outlined based on the submitted data is that decision-making (it is difficult to specify whether at EU or national level, however) is far too slow to follow science with certain impacts occurring as a result: e.g. hindered innovation and food safety, delayed market access etc. This opinion is shared by stakeholders across all categories - mostly by businesses (especially as regards authorisations of substances) but also by several competent authorities.

Stakeholders repeatedly insist on the adoption of EU specific measures for currently uncovered FCMs.

However, the following observations made by the different categories of stakeholders are worth mentioning:

Businesses (manufacturers and/or processors)

The majority of business stakeholders have replied negatively to this question giving material-specific justification for their answer.

Businesses (distributors)

EuroCommerce:
'No, new developments and findings are in many cases taken up by NGOs and then much later addressed by either national or EU policy makers. The crucial point is that there are different interpretations by European and national scientists of results relating to development and research leading to different restrictive regulations.'

Businesses (directly using FCM products)

Food Drink Europe:
'Sometimes yes, but the time needed to incorporate them is too long. For example, the recent EFSA opinion on the "risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials", some concepts considered by EFSA have been available for several years already. Another example is printing inks for which an EU measure has not been adopted yet. Moreover, an alignment between food safety agencies within Europe should be improved. In the case of BPA, different food safety assessment bodies have different scientific conclusions about the safety of BPA, leading to different regulatory provisions in some EU countries vs the EU rule based on the EFSA assessment. An alignment of the scientific opinions between EFSA and the national food safety agencies would be beneficial to maintain consumer confidence in the role of these assessment bodies, and resolve the distortion of the market resulting from the various opinions. We are of the opinion that the new measures should be simpler.'

Competent authorities

The majority of Member States have indicated a positive answer. However, the submitted comments do not allow for trends to be outlined.

European Commission: n/a

EFSA has replied positively and added the following comment:

> 'In general, developments in research are sufficiently taken on board at EU or national level. Future adaptations should be considered based on experience gained from implementation. For now, at EU level, where substances used in plastic food contact materials are specifically regulated, developments in research were taken into account, especially on migration test conditions, modelling, definition of functional barrier and on specific substances such as BADGE, BPA, melamine, etc., Similarly, MS have incorporated research findings in their areas of focus (coatings, paper and boards)'.

Consumers
Both consumer organisations have replied by 'no' to this question.

ANEC:
'The current regulatory standstill in the FCM field at the EU level is in clear contradiction to identified problems (e.g. identified in the Commission roadmap for non-plastics

materials in contact with food dated July 2012 or the discussion about coverage of NIAS), observed food contamination by food packaging (e.g. mineral oils), and activities at the national level (the ESCO report gathered 2800 substances identified in FCMs other than plastics at the Member State level).'

DCC:
'No. Looking from the consumer perspective, it seems as if protection of the manufacturers is more important than protecting the consumers. New developments are not easily implemented. This needs to be prioritised in the future.'

Health/environmental NGOs, represented by ChemTrust, replied by 'no', adding that 'for example, there is no link between the REACH process of identifying of Substance of Very High Concern (SVHC) and impacts on this substance's use in food contact materials'.

Researchers
The 'no' answers among researchers prevail.

Conclusion: Stakeholders (across most categories) are divided in their opinions as to whether new developments in research are sufficiently taken into account by EU and national policy-makers when setting up new FCM rules at EU and/or national level (including 'specific measures' for the articles and materials listed in Annex I to Regulation (EC) No 1935/2004 and 'authorisations' of substances). Some stakeholders (mainly businesses) have indicated cases in which, according to them, scientific knowledge has not been taken into account; the examples are material-specific. The only trend that could be outlined based on the submitted data is that decision-making (it is difficult to specify whether at EU or national level, however) is far too slow to follow science with certain impacts occurring as a result: e.g. hindered innovation and food safety, delayed market access etc.

Q 6 (addressed to Commission/EU-RL on FCMs/, EFSA, health/environmental NGOs, researchers)

> ***Please briefly describe the most important challenges related to studying food contact articles/materials and relevant substances.***

Commission (EU-RL on FCM) - n/a

EFSA has outlined the following challenges:

> 'High number of substances (the need to keep up-to-date with substances really used, need for better cooperation with MS) and non-intentionally added substances (NIAS) including oligomers (what is used is not always what is migrating).'

For **researchers**, including EFSA, 'the unknown' in FCMs constitutes the most important challenge as regards studying their composition, (migration) properties and impacts on human health and the environment.

The following 'unknowns' were identified by **researchers** and **health/environmental** NGOs (the latter being represented by ChemTrust):

- it is largely unknown which substances exactly are used in FCM manufacture and procession, and therefore the development of 'spot' analytical methods for routine and rapid analysis of raw material residues and degradation products in FCMs is recommended;

- not all substances currently used as starting materials are well studied in terms of properties and behaviour and their possible impacts (e.g. toxicity) on human health and the environment,

- non-intentionally added substances (NIASs) whose presence in finished FCMs and chemical structures are unknown and thus risk assessment could not be performed,

- the effects on human health provoked by the (also chronical) exposure to different known and unknown chemicals coming from FCM- and non-FCM sources (e.g. FCMs, cosmetic, cloths, etc), or to multiple sources of one and the same chemical - often referred to as 'cocktails effects'.

- lack of knowledge about chemicals found in recycled materials.

On a more individual basis, ChemTrust also mentions as a scientific challenge the lack of positive lists of chemicals for non-harmonised areas.

Conclusion: 'Unknowns' - such as exactly which substances are used in FCM manufacture and processing insufficiently studied starting substances, non-intentionally added substances (NIASs), the presence of which in finished FCMs and chemical structures is unknown meaning that risk assessment could not be performed, 'cocktail effects' of chemicals to which human beings are exposed, lack of knowledge about chemicals found in recycled materials - are reported (mainly by researchers and health/environmental NGOs) to be the main challenge as regards FCM research.

Q 7 (addressed to Commission /EU-RL on FCMs/)

How would you assess your capacity when it comes to accomplishing your tasks under Article 24 (3) of Regulation (EC) No 1935/2004?

Please, choose between: 'sufficient' or 'insufficient'. In both cases, please briefly explain why.

In accordance with Article 24 (3) of Regulation (EC) No 1935/2004, the EU reference laboratory for materials and articles intended to come into contact with food (EU-RL on FCM) and national reference laboratories[58] assist the Member States in their control activities by contributing to a high quality and uniformity of analytical results.

In their joint response, the Commission services have not formally assessed the capacity of the EU-RL on FCM but have rather indicated the activities of EU-RL as regards its obligation to assist Member States in control activities:

[58] See Part 1 of the study.

'Given the high technical complexity of controlling the safety of food contact materials and in support of developing policy, DG SANTE closely collaborates with the Joint Research Centre, which has the role of the European Union Reference Laboratory (EU-RL) for food contact materials. The JRC works to maintain and where needed to improve the knowledge and tools used by manufacturers of food contact materials to establish compliance e.g. test methods, as well as by enforcement authorities undertaking official controls to verify the safety of materials and articles placed on the market. As part of this collaboration, the JRC in its role as EU-RL contributes to ensuring a high quality and uniformity of analytical results, and assists the National Reference Laboratories (NRLs) in the Member States. In addition, the JRC develops technical guidelines and participates in research and development in the area of method development as well as to underpin new policy developments. The JRC also collaborates with standardisation bodies including CEN and ISO. '

Conclusion: It is very difficult to draw a clear conclusion, but the answer is to be used for the purposes of analysis.

Q 8 (addressed to EFSA)

How would you assess your scientific capacity when it comes to providing independent, reliable and up-to-date scientific knowledge?

Please, choose between: 'sufficient' or 'insufficient'. In both cases, please briefly explain why.

EFSA's reply:

'sufficient - the model of EFSA's scientific panel panels and working groups works well. However, vigilance is required concerning its sustainability in the future as the number of applications, decreasing participation of experts with the requisite expertise, the lack of public laboratories, and the lack of experts in safety assessment may be limiting factors'.

Conclusion: It is very difficult to draw a clear conclusion, but the answer is to be used for the purposes of analysis.

3.1.3. Mapping and assessing the state-of-play as regards EU specific measures under Article 5 (1) of Regulation (EC) No 1935/2004 (checking Relevance/Effectiveness/Utility)

Q 9 (addressed to Commission)

On what grounds does the Commission decide for which of the materials and articles (listed in Annex I) to prepare draft 'specific measures' under Article 5 of framework Regulation (EC) No 1935/2004?

Please explain briefly.

Commission:

'As you are aware, Regulation (EC) No 1935/2004 empowers the Commission to adopt and amend specific measures on special food contact materials and articles. However, only for certain materials, notably plastic materials, specific measures have been introduced at EU level. In order to prioritise the risk management of food contact materials, decisions to progress and adopt further specific measures are based on available information and evidence about the risk to consumer health as well as the internal market and take account of the principles of subsidiarity and proportionality. This is done in a structured manner in applying the COM Better regulation principles.'

Conclusion: It is very difficult to draw a clear conclusion, but the answer is to be used for the purposes of analysis.

Q 10 (addressed to Commission)

How many cases were there in which the Commission has decided to propose the authorisation of a substance against the negative opinion of EFSA and vice versa - positive opinion of EFSA but the Commission refuses to authorise?

Please briefly explain the grounds.

Commission:

'With respect to authorisations of substances the Commission always takes the opinion of EFSA into account, as required by art 11 (2) of Regulation (EC) 1935/2004. Whilst there has been in some cases the need to request further information or clarification from EFSA, the advice provided by EFSA has been sufficient to allow the Commission to make a risk management decision and there are no known circumstances that have forced the Commission to propose a measure that has contradicted an EFSA opinion'.

Conclusion: It is very difficult to draw a clear conclusion, but the answer is to be used for the purposes of analysis.

Q 11 (addressed to competent authorities)

In preparing your Member State's position for the Regulatory Procedure with Scrutiny, do you involve the relevant stakeholders - e.g. consumers, businesses? Is your cooperation with the relevant stakeholders based on legal requirements or not?

If you have replied by 'yes', please provide a link to the legally binding rules.

According to Article 9 of the General Food Law Regulation (EC) No 178/2002 'there shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it'.

All competent authorities have indicated an answer under this question.

The large majority of Member States report that they involve relevant stakeholders - e.g. consumers and businesses in preparing their Member State's position for the Regulatory Procedure with Scrutiny under Regulation (EC) No 1935/2004, which, among other things, leads to the adoption of specific measures and authorisation of substances at EU level. There are, however, Member States saying that they do not (or 'not necessarily') involve stakeholders in this process. Several authorities, involving stakeholders, have specified that consultations are subject to conditions: 'done on a case-by-case basis/not regularly/if necessary/where appropriate and feasible/if there are relevant impacts'.

Not all Member States indicating that they involve stakeholders have specified whether the consultations follow legal requirements at national level. Among the 14 Member States whose answers speak well enough, nine have indicated that they do not follow specific legal requirements and only five have indicated that they do so. Furthermore, where legal requirements are being applied, the partnership models could be 'food safety'-specific or follow general rules on involving stakeholders in policy-making (i.e. in food safety policies but also in other policy areas).

Conclusion: Based on the submitted data, one could conclude that the requirement of Article 9 of the General Food Law Regulation (EC) No 178/2002 (as regards the involvement of stakeholders in the preparation of MS positions for the RPS) is not uniformly met across the Member States.

Q 12 (addressed to competent authorities)

In the absence of 'specific measures' at EU level, has your Member State adopted provisions at national level, including lists of 'authorised' substances?

If your Member State has adopted such provisions, please specify for which articles/materials.

Conclusion: The data reported by Member States is not sufficiently complete to allow for the establishment of reliable statistics on the existence of specific measures at national level[59].

[59] For more statistics on existing national legislation, see the European Commission table (last updated in 2014).

Q 13 and 14 (considered together)

Q 13 (addressed to businesses)

In your FCM sector, what rules do you comply with in the absence of 'specific measures' at EU level for the respective article/material? What are the main challenges related to such compliance?

Please disregard this question, if irrelevant.

Q 14 (addressed to businesses)

In your sector, is there national legislation (inside or outside the EU) laying down lists of 'authorised' substances that you should comply with? If you have replied by 'yes', please, specify the country.

Businesses (manufacturers and/or processors)

All relevant businesses (i.e. those manufacturing/processing FCMs for which EU specific measures are not available) have replied to these questions by indicating sources of rules that they comply with. Businesses naturally tend to report that they apply Regulation (EC) No 1935/2004 and Regulation (EC) No 2023/2006 (on good manufacturing practice) which lay down common requirements with which all FCMs listed in Annex I to Regulation (EC) No 1935/2004 should comply.

Observations on FCMs not covered by EU specific measures

In the absence of specific measures adopted at EU level, most often businesses comply with 'rules' deriving from a variety (also combination) of sources. Businesses report to most often comply with national (Member States') legislation and industry self-regulation, followed by EU specific measures for plastics, Council of Europe resolutions, EU specific measures for ceramics and legislation of third countries (such as USA, China and Switzerland). Some of these sources of rules (e.g. industry self-regulation, EU specific rules for plastics and ceramics, CoE resolutions) are complied with by businesses on a voluntary basis.

Based on the information reported by business stakeholders, the majority of businesses not currently covered by EU specific measures, such as rubbers, adhesives, silicones, paper & board, printing inks, (can) coatings, metals alloys (steel for packaging), waxes and additives, are faced with positive lists for authorised substances. The relevant lists are most often established by EU Member States but also by third countries (USA, CH, China).

Individual manufacturers of FCMs are supposed to comply with the rules applicable to the material that they are manufacturing, but also with the rules regulating other materials to which they contribute. This is the case, for example, for silicones and additives which, among other things, are used in the production of paper & board, printing inks, rubbers, adhesives. They are thus supposed to comply with the rules for

silicones and additives, but also with the rules applicable to paper & board, printing inks, rubbers etc.

Examples:
The manufacturers of silicones report[60] that their members comply with the following set of rules relevant to the FCMs to which silicones are supplied (the list is not exhaustive):

Type of Materials	Use Type	Positive List
Adhesives	Silicones as additives or silicone rubber sealants	BfR IV, French Brochure 1227/Decree of 25 November 1992 (for silicones)
Cork	Silicones as additives or coatings	CoE, Dutch Warenwet chapter X, French Brochure 1227/Decree of 25 November 1992 (for silicones)
Rubber	Silicone as additives in rubber	BfR XXI, Dutch Warenwet chapter III, French Brochure 1227/Decree of 4 November 1994 (for silicones as additives)
Paper and board	Silicones as additives or coatings	CoE, BfR XXVI, Dutch Warenwet chapter II, French Brochure 1227/Decree of 25 November 1992 (for silicones)
Plastics	Silicones as additives	10/211/EU (Silicone additives in plastics) BfR XIV for plastic dispersions, Brochure 1227: Decree of 2 January 2003 (plastics)
Printing inks	Silicones as additives	Swiss ordinance; German ordinance under preparation, French Brochure 1227/Circular 176 (for colorants) and Decree of 25 November 1992 (for silicones)
Anti-stick coatings	Silicone fluids as additives, resins and rubber to form coatings	CoE, BfR LI Dutch Warenwet Chapter X, French Brochure 1227 Decree of 25 November 1992 (for silicones), Spanish Decree of 2011
Silicones	Silicone fluids, resins, elastomers	CoE, BfR XV, for silicone elastomers, French Brochure/ Decree of 25 November 1992 (for silicones), Spanish Decree of 2011, Dutch Warenwet chapter III, Italian Decreto Ministeriale 21/03/73

[60] The answer is indicated under Q 14: 'In your sector, is there national legislation (inside or outside the EU) laying down lists of "authorised" substances that you should comply with? If you have replied by "yes", please, specify the country.'

The manufacturers of additives report that they comply with the following set of rules relevant for the FCMs to which additives are supplied:

Type of materials	Positive list
Adhesives	Germany: BfR 14 USA: FDA
Rubbers	Germany: BfR 21 The Netherlands: FDA, Dutch Warenwet Chapter III Italy: Italian Ministerial Decree of 21 March 1973 as amended
Paper and board	Germany: BfR 36/1-3 BfR 14 The Netherlands: FDA Dutch Warenwet Chapter II Italy: Italian Ministerial Decree of 21 March 1973 as amended USA: FDA
Printing inks	Switzerland: Swiss Ordinance
Silicones	Germany: BfR 15
Varnishes and coatings	Germany: BfR 14 The Netherlands: Dutch Warenwet Chapter X Italy: Italian Ministerial Decree of 21 March 1973 as amended USA: FDA
Waxes	Germany: BfR 25
	USA: FDA

Observations on plastics (covered by EU specific measures)

Although covered by specific measures, plastics manufacturers also indicated an answer under this question, stating that some MS (e.g. Germany and the Netherlands) 'do have at national level an additional requirement regarding the authorisation of polymerisation catalysts and their breakdown products .... In addition, those substances not covered by positive listing are risk assessed by the manufacturers in accordance with internationally recognised scientific principles on risk assessment'.

Compliance challenges

Not all businesses have provided information as to the main challenges related to multiple-source compliance. Most often businesses report on the uncertainty created by the differences in national rules with effects on compliance, such as:

- the acceptance of businesses' compliance (also self-regulatory) approaches by national enforcement authorities is not guaranteed;
- the multiplication of costs related to ensuring compliance (including petitioning for authorisations) under differentiating national rules.

Conclusions under Q 13 and Q 14:

Businesses, manufacturing/processing FCMs currently uncovered by EU specific measures, report to most often comply with national (Member States') legislation and industry self-regulation, followed by EU specific measures for plastics, Council of Europe resolutions, EU specific measures for ceramics and legislation of third countries (such as USA, China and Switzerland). Some of these sources of rules (e.g. industry self-

regulation, EU specific rules for plastics and ceramics, CoE resolutions) are complied with by businesses on a voluntary basis. Businesses that are currently covered by EU specific measures - plastics in particular - also report on national 'additional requirements at national level regarding the authorisation of polymerisation catalysts and their breakdown products'.

Based on the information reported by business stakeholders, the majority of businesses currently uncovered by EU specific measures, such as rubbers, adhesives, silicones, paper & board, printing inks, can coatings, metals & alloys (steel for packaging), waxes, additives, woods are faced with positive lists for authorised substances. The relevant lists are most often established by EU MS but also by third countries (USA, CH, China etc.).

Individual businesses are supposed to comply with several rules not only for the material they are manufacturing but also for materials to which they supply.

As a main challenge related to compliance with 'multiple-source' requirements, businesses tend to outline the uncertainty created by differences in national rules with effects on compliance. In particular, businesses are worried that the acceptance of their compliance (also self-regulatory) approaches by national enforcement authorities is not guaranteed. Furthermore, the multiplication of costs related to ensuring compliance (including petitioning for authorisations) under differentiating national rules is also underlined by several businesses as a pertinent implementation challenge.

Q 15 (addressed to businesses, consumers, health/environmental NGOs)

Do you think that the absence of 'specific measures' at EU level for some articles and materials negatively affects the internal market and safety of FCMs? Please, reply by 'yes' or 'no'.

If you have replied by 'yes', please briefly explain why.

Please disregard this question, if it is irrelevant to the article/material your members are working on.

Almost all relevant respondents have indicated an answer under this question.

Businesses (manufacturers and/or processors)

Businesses (both covered and not covered by EU specific measures) almost unanimously state that the absence of EU specific measures for most of the FCMs listed in Annex I to Regulation (EC) No 1935/2004 has negative effects on the internal market and food safety.

- **on internal market**

  In the absence of EU specific measures for the articles/materials listed in Annex I to Regulation (EC) No 1935/2004, Member States are allowed to maintain/adopt such measures at national level. These national specific rules might vary from one MS to another which implies the application of the mutual recognition principle.

A large majority of businesses (currently not covered by EU specific measures) consider that where the absence of EU specific measures has resulted in the adoption of national measures the effective functioning of the internal market has been distorted, which is mainly due to the different way in which Member States apply the mutual recognition principle.

Furthermore, businesses report on multiplication of the costs that they incur to demonstrate compliance under different national enforcement regimes for one and the same material. For example, a business operator manufacturing or processing a material/article not covered yet by EU specific measures might face a compliance situation where a substance is authorised in one Member State but not authorised yet, or forbidden, in another Member State. For businesses, the multiplication of costs leads to loss of competitiveness. Some business stakeholders express their fear that national measures might be used as a protective measure at national level. Almost half of businesses declare that where the absence of EU specific measures has resulted in national rules, compliance is checked (i.e. enforcement is ensured) by competent authorities following different approaches as regards e.g. sampling, migration testing, risk assessment, interpretation of results etc., which creates compliance uncertainty, disputable results and increased compliance costs.

– **on food safety**

Although with their 'yes' answers the large majority of businesses have reported that food safety is also negatively affected by the absence of EU specific measures for the majority of FCMs listed in Annex I to Regulation (EC) No 1935/2004, individual business respondents have made comments as regards food safety. Comments go in different directions and no clear trend could be outlined. Wherever specific measures were not adopted at national level, as a general rule, businesses apply the so-called 'self-assessment' (as a form of industry self-regulation) or other sources of rules[61] which, however, do not constitute a legal basis for enforcement by the national competent authorities thus creating risks for self-regulation (voluntary compliance) to be rejected by competent authorities. Furthermore, the lack of EU specific measures (i.e. a uniform safety standard) raises concerns of the safety of imported FCMs and packed food.

Businesses (distributors)

EuroCommerce:
'Yes, an example is the absence of uniform rules for the utilisation of BPA in other uses than for food contact materials out of plastic. France, Belgium and Denmark have adopted further laws to limit BPA. Additionally the printing inks directive launched by Germany (mineral oil contamination from recycled cardboard, primary aromatic amines limit) can create new barriers.'

Businesses (directly using FCM products)

[61] See observations under Q 13 and Q 14.

Food Drink Europe:
'Yes, we think that the absence of specific measures at EU level for the articles and materials negatively affects the internal market and safety of FCMs. In the absence of specific measure at EU level, some MS consider establishing national rules that can create a new and unjustifiable burden for local companies or importers, for example the German draft Ordinance on printing inks (in discussion) and the BPA ban in France (enforced). It is also more difficult for smaller companies to conduct a proper risk assessment. Having more harmonised rules at EU level would help to obtain more homogeneity in the risk assessment of FCM.'

Consumers
Consumer organisations state that the lack of EU specific measures for some FCMs have negative effects on consumers whereby ANEC refers to the Commission's 2012 Roadmap for non-plastics materials in contact with food which, in ANEC's words, identifies negative effects on both the functioning of the internal market (by market fragmentation as a result of national rule making) and FCM safety.

Health/environmental NGOs, represented by ChemTrust, report that 'the lack of harmonised measures on e.g. paper, card, ink, coatings, adhesives means that their chemical content is essentially unregulated, and makes it extremely difficult for any enforcement action to be carried by the regulator. The internal market is also disrupted by different rules in different Member States. Mutual recognition will not solve this problem, as it will penalise those Member States who attempt to regulate (e.g. inks), forcing a race to the bottom'.

Conclusion:

Businesses (both those covered and not covered by EU specific measures) almost unanimously state that the absence of EU specific measures for most of the FCMs[62] has negative effects on the internal market and food safety. A large majority of businesses (currently not covered by EU specific measures) consider that where the absence of EU specific measures has resulted in the adoption of national measures the effective functioning of the internal market has been distorted, which is mainly due to the different way in which the EU Member States apply the mutual recognition principle. Furthermore, businesses report on multiplication of the costs they incur to demonstrate compliance under different national enforcement regimes for one and the same material - e.g. a substance might be authorised in one Member State but forbidden (or not authorised yet) in another. For businesses, the multiplication of costs leads to loss of competitiveness. Almost half of businesses declare that where the absence of EU specific measures has resulted in national rules, compliance is checked (i.e. enforcement is ensured) by competent authorities following different approaches as regards e.g. sampling, migration testing, risk assessment, interpretation of results etc., which creates compliance uncertainty, disputable results and increases compliance costs.

Wherever such standards were not adopted at national level, as a general rule, businesses apply the so-called 'self-assessment' (as a form of industry self-regulation) or other

[62] Listed in Annex I to Regulation (EC) No 1935/2004.

sources of rules which, however, do not constitute a legal basis for enforcement by the national competent authorities thus creating risks for self-regulation (voluntary compliance) to be rejected by MS' authorities. Furthermore, for some businesses the lack of EU specific measures (i.e. a uniform safety standard) raises concerns of the safety of imported FCMs and packed food.

Consumer organisations state that the lack of EU specific measures for some FCMs has negative effects on consumers.

Health/environmental NGOs, report that the lack of harmonised measures on some FCMs means that their chemical content is essentially unregulated, and makes it difficult for enforcement.

Q 16: (addressed to businesses, competent authorities, Commission, EFSA, consumers, health/environmental NGOs, researchers)

From your perspective, what articles and materials should be further regulated and at what (EU or national) level?

Please explain the reasons both in terms of FCM safety and functioning of the internal market.

Under this question, but also repeatedly under other questions, the following categories of stakeholders - businesses, competent authorities, consumers, health/environmental NGOs, scientific community - almost unanimously voice support for adoption of specific measures at EU level for all or for several of the materials listed in Annex I to Regulation (EC) No 1935/2004. Around one third of the stakeholders participating in the survey have indicated that EU specific measures for *all* FCMs are needed while others were more selective and pointed to particular food contact materials in need of specific measures at EU level.

Businesses (all three categories)

2 out of the 22 business organisations participating in the survey have not indicated an answer under this question.

Six businesses organisations [63] are in favour of adoption of EU specific measures for all FCMs that are currently not covered by specific measures. Only two business stakeholders consider that none of the currently non-harmonised FCMs is in need of EU specific measures.

In addition, most business respondents have quoted particular FCMs in need of specific measures and some businesses have prioritised the adoption of specific measures.

Thus, in general terms, businesses consider that specific measures at EU level should be adopted according to the following priority line:

[63] The six business organisations that answered this question.

- paper & board[64] (quoted by 12 businesses),

- printing inks (quoted by 10 businesses),

- varnishes & coatings[65] (quoted by 9 businesses),

- adhesives, rubbers[66], glass, metals & alloys (quoted by 8 businesses each),

- cork, silicones, and waxes (quoted by 7 businesses each), and

- ion-exchange resins, textile, and wood (quoted by 6 businesses each).

The above figures show that not only the very manufacturer/processor of a given material is in favour of adoption of EU specific measures for this particular material, but also industries manufacturing/processing other food contact materials. This can be explained by the fact that several individual FCMs are used in the manufacture/processing of other food contact materials and articles.

In addition, individual businesses also suggest that the following should be regulated:

- those FCMs with a more chemical content complexity and where conditions of use (time, temperature, food type, etc.) pose a higher risk;

- NIASs in packaging materials - for instance the chemical effects of recycling on the quality of packaging materials should be better considered (e.g. paper, cardboard, plastics);

- substances for which the estimated dietary exposure might indicate a potential exceedance of the corresponding human exposure threshold values;

- mineral oil contamination of food from recycled cardboard;

- primary aromatic amines in printing inks;

- Bisphenol A;

- recycled materials - without further specification.

The arguments put forward by businesses refer to both: ensuring (even restoring) the effective functioning of the internal market and food safety as regards these FCMs.

Competent authorities

4 out of the 28 Member States participating in the survey have not responded to this question[67].

[64] Individual businesses have added that recycled paper & board, and in particular mineral oils from recycled paper & board should be regulated.
[65] Including can coatings.
[66] Including thermoplastic elastomers.
[67] Nevertheless, a majority of these four countries have expressed (under other questions) their opinion in favour of further EU harmonisation. However, these comments are insufficiently

Eight Member States[68] are in favour of adoption of EU specific measures for all FCMs that are currently not covered by specific measures. Only one Member State explicitly considered that there is no need for adoption of EU specific measures for any of the FCMs that are currently not covered by specific measures. In addition, most MS respondents[69] have quoted particular FCMs in need of specific measures and some MS have prioritised the adoption of specific measures.

Thus, in general terms, Member States consider that specific measures at EU level should be adopted according to the following priority line:

- paper & board [70] (quoted by 19 Member States)

- printing inks (quoted by 12 Member States)

- varnishes & coatings (quoted by 14 Member States)

- metals & alloys [71] (quoted by 13 Member States)

- glass, rubbers, silicones and wood (quoted by 10 Member States each)

- adhesives and cork (quoted by 9 Member States each)

- ion-exchange resins, textiles and waxes (quoted by 8 Member States each)

In addition, individual Member States also suggest that the following should be regulated:

- FCMs that are currently covered by specific measures at EU level:
    - ceramics - amendment/revision of existing EU specific measures on ceramics[72] is required;
    - plastics - the positive list established by the existing EU specific measures on plastics[73] should be revised in the light of current state of knowledge and in the context of CLP-Regulation/REACH; the scope of the EU specific measures on plastics should be extended to cover colorants, solvents and all polymer production aids);

concrete, and could not be taken into account under this question aimed at identifying which FCMs should be further regulated at EU level by the adoption of specific measures.

[68] Of those giving an answer under this question.

[69] Including some of those who declared themselves in favour of adoption of specific measures for all FCMs.

[70] Individual businesses have added that recycled paper & board, and in particular mineral oils from recycled paper & board should be regulated.

[71] Including stainless and non-stick steel and coated metals.

[72] Directive 84/500/EEC on ceramics.

[73] Regulation (EU) No 10/2011 on plastics.

  - active and intelligent materials - the existing EU specific measures on active and intelligent materials[74] should be reviewed and a positive list of authorised substances should be adopted;
  - cellulosic products (without further specifications)

- **Individual substances** such as: Bisphenol A, SFVS, but also NIASs, and biocides (migration limits for biocides used in FCMs should be set according to the so-called 'biocides' regulation[75])

- Materials that are currently not included in Annex I to framework Regulation 1935/2004
  - stone
  - enamel

Others:

- requirements for organoleptic characteristics of FCMs are necessary
- Multilayer-Multi-Materials (the so-called 'MMM')

The arguments put forward by competent authorities refer to both proper functioning of the internal market and food safety, but also enforcement of compliance.

Commission:

'Besides regulatory measures the European Commission also considers in this context alternative instruments, such as strengthening industry self-regulation or mutual recognition.

Accordingly, and taking into account the interests of stakeholders, including EU Member States, industry organisations and consumers, DG SANTE has tasked the JCR to carry out a "base-line" study in order to provide a comprehensive description of the current situation concerning food contact materials for which there are no specific measures at EU level. The study will allow the European Commission to assess what, if any, possible steps need to be taken in the future concerning the regulation of FCMs … '.

The Commission's evaluation of the final report of the JRC study is ongoing.

EFSA:

'outside EFSA's remit'

Consumers

ANEC considers as a matter of priority, and as a minimum the adoption of EU specific measures for paper & board, printing inks, coatings and metals, while the Danish Consumer Council would like to see all 17 FCMs regulated more intensively and horizontally.

[74] Regulation (EC) No 450/2009 on active and intelligent materials.
[75] Regulation (EU) No 528/2012 on biocides.

Health/environmental NGOs
ChemTrust speaks in favour of EU specific measures for all FCMs.

Researchers
The majority of researchers have indicated an answer under this question. Two researchers have recommended adoption of specific measures for all FCM that are currently not covered by specific measures at EU level. The FCMs most often quoted by researchers are: paper & board[76], printing inks, silicones, adhesives, but also barrier compounds, Bisphenol A and its analogues, additives and packaging (without further specifications). Arguments put forward by researchers in favour of more regulation at EU level refer to safety reasons but also to enforcement needs saying that effectiveness of controls could be better ensured via a centralised regulatory and foresight approach.

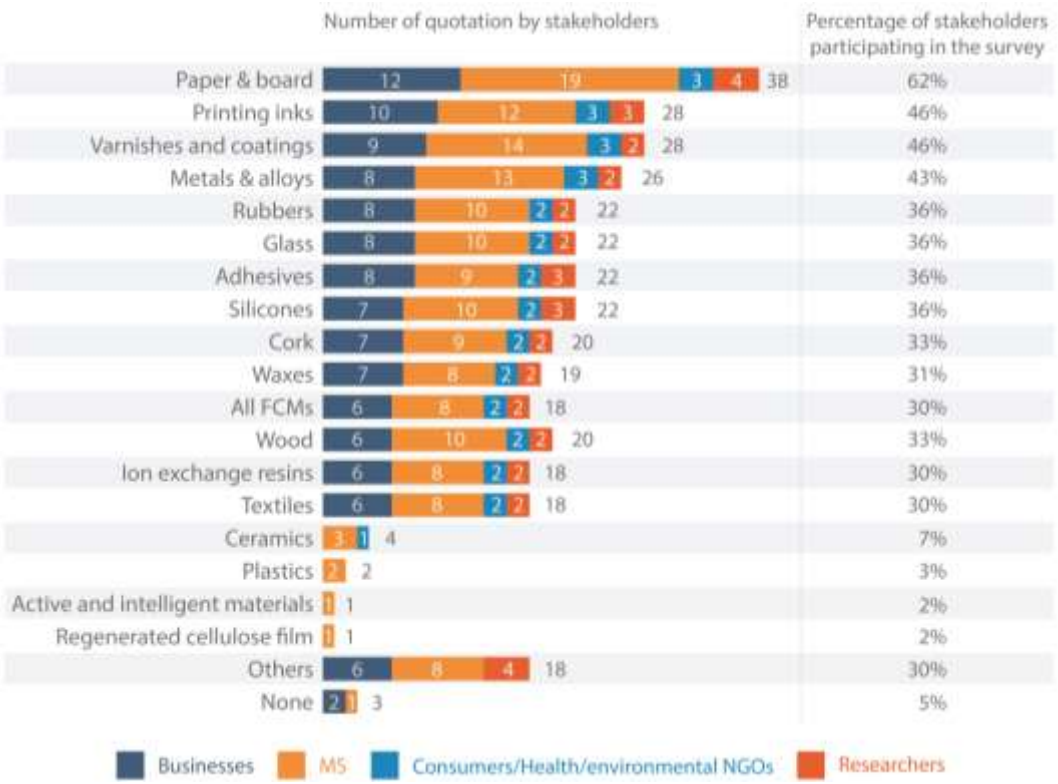
Conclusion:

In total, 18 (out of the 61) stakeholders participating in the survey have voiced support for adoption of EU specific measures for all (non-harmonised) FCMs. The majority of stakeholders have specified particular FCMs in need of EU specific measures.

The responses submitted by stakeholders (across most categories) show that paper & board (including recycled paper) is the number one candidate for adoption of specific measures at EU level, as explicitly recommended by more than half of the stakeholders participating in the survey. See the preferences expressed by stakeholders in Graph 2.

[76] Also paper for cooking food.

Graph 2 : FCM-candidates for further harmonisation at EU level



* Several respondents have indicated more than one answer, and therefore, the sum of percentages exceeds 100 %.

Individual stakeholders have come up with concrete ideas as regards harmonised FCMs, particular substances or materials that are not included in Annex I to framework Regulation (EC) No 1935/2004.

Stakeholders recommend adoption of EU specific measures for reasons related to the restoring and effective functioning of the internal market and food safety. As regards the scope and approach of the suggested EU specific measures and other recommendations, see Part 4 of this study.

3.1.4. Mapping and assessing current rules on 'good manufacturing practice' and related documents (declarations of compliance) (checking Effectiveness)

Q 17: (addressed to businesses)

Has your sector established specific 'good manufacturing practice (GMP)' guidelines for the relevant article/material?

If you have replied by 'yes', please indicate a link to these guidelines.

Please disregard this question if not relevant.

Almost all **businesses (manufacturers and/or processors)** have indicated an answer.

The large majority of businesses report to have established specific 'good manufacturing practice' guidelines for the relevant FCM at sector level, i.e. a common approach to be followed by member companies operating in the relevant FCM industrial sector.

Some businesses mention that guidelines are established also at company level. At the time when the data submitted under this questionnaire was processed, some sectors - such as glass and printing inks - reported to be in a process of revising/finalising their industry guidance on GMP for FCMs.

Conclusion: see at the end of this block of questions

Q 18 (addressed to businesses)

From your perspective, are the current EU and sector-specific GMP rules sufficient to ensure safety of the articles and materials?

Please reply by 'yes' or 'no'.

If you have replied by 'no', please, briefly describe why the current EU and sector-specific GMP rules for the particular article/material are insufficient.

Almost all **businesses (manufacturers and/or processors)** have indicated an answer under this question.

The majority of businesses consider that the current EU and sector-specific GMP rules are sufficient to ensure safety of the relevant FCM. Those replying by 'no' indicate that the rules established in Regulation (EC) No 2023/2006 on GMPs but also the general safety requirements of Article 3 of Regulation (EC) No 1935/2004 are 'general' and/or 'vague', i.e. no strict action is prescribed so that compliance could be ensured. In particular, printing ink manufacturers point out that 'Increasingly, industry and control authorities are faced with the challenge of interpreting whether materials for which no specific measures exist comply with the very general requirements of the framework Regulation, particularly its Article 3. Apparently, attempts have not always been successful, and the result was food scares related to migration of substances from food packaging, widely reported in the European press'.

Businesses (distributors)

EuroCommerce:
'not conclusive feedback.'

Conclusion: see at the end of this block of questions

Q 19: (addressed to businesses) (complementary question)

In the absence of EU 'specific measures' for the FCMs that your sector is working on, are there any other requirements for 'Declarations of compliance' (DoCs) and relevant 'appropriate documentation' that your members are supposed to comply with? Please specify the authority/authorities laying down these requirements.

Please disregard this question if not relevant.

Almost all **businesses (manufacturers and/or processors)** have indicated an answer under this question.

However, only some businesses have formally responded to the question, focusing on DoCs. As under Q 13 and Q 14, the majority of businesses tend to report on the variety of sources establishing rules that they should comply with (in the absence of specific measures at EU level for the relevant FCM) to prove compliance. The sources of compliance requirements are reconfirmed: national (Member States') legislation (with requirements for DoCs), industry self-regulation, followed by EU specific measures for plastics, Council of Europe resolutions, EU specific measures for ceramics and legislation of third countries (such as USA, China and Switzerland). Compliance with such rules is mostly sought by the next in the supply chain but also by enforcement authorities.

Conclusion: see at the end of this block of questions

Q 20: (addressed to competent authorities) (complementary question)

In the absence of EU 'specific measures' for the articles and materials listed in Annex I to Regulation (EC) No 1935/2004, has your Member State adopted provisions laying down a requirement for 'Declarations of compliance' and relevant 'appropriate documentation' to be made available by businesses? Please, specify the authority laying down these requirements.

All Member States have replied to this question.

Only individual MS report to have adopted requirements for DoCs for all or some of the FCMs currently not covered by EU specific measures.

Conclusion for this block of questions (Q 17-20 above):

The large majority of **businesses (manufacturers and/or processors)** report to have established specific 'good manufacturing practice' guidelines for the relevant article/material established at sector level, i.e. common for the member companies operating in the relevant FCM industrial sector. The majority of businesses consider that the current EU and sector-specific GMP rules are sufficient to ensure safety of the relevant FCM. Those replying by 'no' indicate that the rules established in Regulation (EC) No 2023/2006 on GMPs, but also the requirements of Article 3 of Regulation (EC) No 1935/2004, are 'general' and/or 'vague', i.e. no strict action is prescribed so that compliance could be ensured.

Only individual Member States report to have adopted requirements for DoCs for the FCMs currently not covered by EU specific measures.

Businesses reconfirm the variety of sources they comply with without putting strict focus on requirements for DoCs. Justification of compliance (in the form of DoC or in another form) is mostly sought by the next in the supply chain but also by enforcement authorities.

3.2. Assessment of the implementation of current EU FCM rules

3.2.1. Assessment of the implementation of good manufacturing practices and related documents (declarations of compliance) (checking Effectiveness and Efficiency)

Q 21 (addressed to businesses)

> ***From your perspective, please describe the main challenges (e.g. costs for risk assessments) related to the implementation of the current EU and sector-specific GMP rules, and relate them to the different types of enterprises: large-, medium-, small- and micro-sized ones.***

Almost all businesses have indicated an answer under this question.

The large majority of **businesses (manufacturers and/or processors)** report that the most important challenge related to the implementation of current EU and sector-specific GMP rules are the costs associated with ensuring compliance. Testing procedures (such as migration testing, risk assessment etc) are the main source of compliance costs together with the costs associated with petitioning for authorisations. The main issue of concern as regards authorisation-related costs is the multiplication of petitioning procedures for the same substance under differing national legislations and hence the multiplication of costs; furthermore, petitioning procedures (often available in national languages only) may vary from one Member State to another which implies additional costs for businesses. On petitions for authorisations, see also the observations under Q 24 and 25.

Several businesses consider that current testing and authorisation procedures lead to limited (or delayed) access to new markets, loss of competitiveness and innovation in Europe without necessarily guaranteeing consumer safety. Businesses tend to attribute these challenges to the lack of EU specific measures for some FCMs and keep on insisting on the adoption of such measures at EU level.

Some businesses also report on industry-specific challenges which are difficult to be summarised.

Individual businesses have related the outlined challenges with the size of enterprises in their FCM sector. Those who have addressed this question, report that SMEs are affected significantly by the challenges outlined above, and in particular (as quoted by individual businesses) the implementation of management system, staff training etc.

Businesses (distributors)

EuroCommerce:
'The fragmentation of the supply chain can hamper efficient and effective information flow.
- To match the objective on the use of recycled materials with the precautionary principle
- The challenges are independent from enterprise sizes but are on the level of testing method and analytical approach.'

Conclusion: see at the end of this block of questions.

Q 22 (addressed to businesses and competent authorities)

> ***From your perspective, is the very availability of a 'Declaration of compliance' and 'appropriate documentation' ensuring that the particular article/material (covered or not by EU 'specific measures') complies with the rules applicable to this article/material?***
>
> ***Please reply by 'yes' or 'no'.***
>
> ***If you have replied by 'no', please briefly describe why.***

Businesses (manufacturers and/or processors)

The majority of businesses consider that the very availability of DoCs ensures compliance with the rules.

Those replying by 'no' indicate that DoCs are necessary but not sufficient alone: individual businesses recommend that this document should be supported by certifications from third parties (e.g. auditing, surveillance plans). This group of businesses also report on missing information in the DoCs as regards composition, testing performance and relative supporting documents. Some businesses indicating a positive answer also comment on the quality of information submitted in the DoCs throughout the whole supply chain which they consider important as regards ensuring safety and compliance.

Businesses (distributors)

EuroCommerce:
'Yes, it's a business commitment and it show that this specific regulation has been taken into account by the suppliers (among all the others regulation related to the product). However, it needs to be noted that for the responsible supplier of the FCM, the rules leave room for interpretation regarding the chemical analysis (different migration levels in member states for heavy metals etc.) hence compliance could be challenged.'

Businesses (directly using FCM products)

Food Drink Europe:

'It was indicated that the Declaration of Compliance needs to be followed by audits and surveillance plans are key elements in order to be effective. Furthermore it was highlighted that the quality of the DoCs available on the market is low. This has been reported recently in a report by Nordic authorities, and in an oral presentation given by FSAI (Ireland) at a recent food contact conference (80% of DoC found to be "significantly non-compliant" on a sample of 176 - Smithers Pira conference – Dec 2015). A DoC ensures compliance of the material only when it is appropriately created, with enough details about the materials and substances used, and accompanied by appropriate supporting documents. Overall, suppliers should get a better knowledge of applicable regulations in order to be able to produce better DoCs.'

Competent authorities

Member States are divided in their opinions as to whether the very availability of DoCs and supporting documents ensures compliance with applicable rules. Even though DoCs and supporting documents are generally considered an important basis for enforcement work, a large majority of competent authorities are of the opinion that DoCs and supporting documents are not always complete and reliable, which complicates the enforcement work of control bodies. MS report that often further analytical work is needed to make sure that the 'declared compliance' reflects reality, which increases enforcement costs. Some Member States point to problems with the quality of documentation submitted by importers of FCMs.

Conclusion: see at the end of this block of questions

Q 23: (addressed to businesses, competent authorities, Commission, EFSA, consumers, health/environmental NGOs)

> ***From your perspective, are the current EU FCM rules sufficient to ensure traceability in the supply chain? Please reply by 'yes' or 'no'.***
>
> ***If you have replied by 'no', please briefly describe why.***
>
> ***Please also comment on the main challenges related to the implementation of traceability rules and relate them to the different types of enterprises: large-, medium-, small- and micro-sized ones[77].***

It should be noted that some categories of stakeholders to which this question was addressed, (especially businesses and competent authorities), perceive DoCs as instruments ensuring traceability. However, under Regulation (EC) No 1935/2004 traceability is limited to identifying the business from which goods have been received and to which they have been provided and does not depend on the availability of DoCs. Nevertheless, the responses from stakeholders among businesses and competent authorities show that they perceive DoCs and the information included therein on composition and compliance of the goods as integral part of traceability. The availability and/or quality of DoCs therefore influences the assessment of achieving traceability throughout the production and distribution chain. See the details below.

[77] This question varies slightly for each category of stakeholders: businesses and Member States.

Businesses (manufacturers and/or processors)

Almost all businesses have indicated an answer under this question.

The majority of businesses state that current EU FCM rules are sufficient to ensure traceability.

Individual businesses which have added comments here raise concerns as regards the lack of requirements for proper identification (e.g. code marking) of FCMs (i.e. relevant batches, lots etc), so as to indicate manufacturer, origin etc. Some businesses also report on traceability problems as regards the quality of DoCs and imported products.

Businesses (distributors)

EuroCommerce:
'The traceability requirements prescribed by the current legislation are sufficient. Full chain traceability is ensured when all operators in the supply chain take up their responsibility, hence no additional rules are needed.'

Businesses (direct users of FCM products)

FoodDrinkEurope:
'Yes'

Competent authorities

All competent authorities have indicated an answer under this question.

The large majority of competent authorities state that current EU FCM rules are sufficient to ensure traceability. However, even though indicating a positive answer, enforcement bodies often report on problems when it comes to implementation of the traceability rules without referring to a particular FCM sector. In particular, problems arise when the relevant documentation (DoCs and supporting documents) is not complete (or is even not available), and in particular, as far as imports of FCMs from third countries are concerned.

Under this and other questions some competent authorities point to insufficient knowledge demonstrated by business operators as regards ensuring compliance (knowledge of applicable rules, preparation of reliable compliance documentation (such as DoCs and supporting documents), etc.

Some competent authorities raise concerns as regards the lack of requirements for proper identification (e.g. code marking) of FCMs (i.e. relevant batches, lots etc), so as to indicate manufacturer, origin etc.

Some competent authorities come up with recommendations, which are considered in Part 4 of the study.

Commission: n/a

EFSA:

'outside EFSA's remit'

Consumers

Both consumer organisations have indicated an answer under this question and it is negative.

They are of the opinion that there is a lack of knowledge of what chemicals are used where in the supply chain, which hinders traceability.

DCC: 'No. There's a need to find out which chemicals are used and where. Since this overview is missing, no one really knows which chemicals consumers are being exposed at what levels. This leads to a lack of traceability down the supply-chain'.

ANEC: 'No. There isn't sufficient knowledge on chemicals used in the current complex supply chains. In the case of FCMs, the 2012 European Commission Roadmap 'Food Contact materials – Specific provisions for products other than plastics- implementing measure' already referred to the lack of risk assessment for substances in products and the difficulties that exist in carrying it out'.

Health/environmental NGOs

ChemTrust has replied by 'no', thus confirming the position of consumers that 'particularly in non-harmonised areas it is clear that the supply chain will generally have little idea what is in food contact materials (examples given by Co-op Denmark at the Parliamentary hearing on 26th Jan 2016[78] where suppliers claimed certain chemicals weren't used, but analysis showed that they were)'. ChemTrust also suggests that 'commercial confidentially is an issue'.

General conclusion for this block of questions (Q 21-23 above):

On GMPs
The large majority of businesses report that the most important challenge related to the implementation of current EU and sector-specific GMP rules are the costs associated with ensuring compliance with testing procedures and petitioning for authorisations of substances (under differing national regulatory regimes) topping the chart. Several businesses consider that current testing and authorisation procedures lead to limited (or delayed) access to (new) markets, loss of competitiveness and innovation in Europe without necessarily guaranteeing consumer safety. Businesses tend to attribute these challenges to the lack of EU specific measures for some FCMs and keep on insisting on the adoption of such measures at EU level.

Declarations of compliance
In total, based on replies of businesses and competent authorities to which this question was addressed, the 'yes' answers prevail, meaning that the majority of these two categories of stakeholders consider that the very availability of DoCs is sufficient to ensure that the FCM complies with relevant rules. However, additional comments by

[78] The respondent makes a reference to the Workshop on 'Food contact materials – how to ensure food safety and technological innovation in the future' organised by European Parliament Policy Department A, Economic and Scientific Policy.

businesses and competent authorities show the 'yes' position is conditional and has its limits (see above for details). Both businesses and competent authorities tend to agree that DoCs and supporting documents are a necessary tool for ensuring compliance (for businesses) and checking compliance (for competent authorities), provided that the submitted information is complete and reliable. Furthermore, both businesses and competent authorities indicate problems with the information contained in DoCs and relevant supporting documents, as regards accuracy, completeness, and hence their reliability. The problem seems to be exacerbated in the case of DoCs accompanying imported FCMs.

Thus, for several businesses and competent authorities, DoCs and supporting documents are necessary but not sufficient alone to prove compliance.

Traceability

Stakeholders are not united in their opinions as to the potential of current rules to ensure FCM traceability: businesses and competent authorities indicate mostly positive answers, while consumers and health/environmental NGOs give negative answers.

Although replying with 'yes', several businesses and competent authorities have made comments pointing to traceability problems. In particular, such problems arise when the relevant documentation (DoCs and supporting documents) is not complete (or is even not available), and in particular, as far as imports of FCMs from third countries are concerned. Some businesses and competent authorities raise concerns as regards the lack of requirements for proper identification (e.g. code marking) of FCMs (i.e. relevant batches, lots etc.), so as to indicate manufacturer, origin etc.

Consumer and health/environmental organisations are of the opinion that there is a lack of knowledge of what chemicals are used where in the supply chain, which hinders traceability or even makes it impossible.

3.2.2. Assessment of compliance and enforcement costs generated by the implementation of relevant FCM rules (checking Efficiency)

Q 24 (addressed to businesses)

From your perspective, how would you assess the 'compliance costs' generated by the current EU FCM rules and national FCM rules (please, also take into account the costs related to the preparation of applications for 'authorisation' of substances at EU or national level)?

For each set of rules (EU and national), please assess the costs as 'very high' or 'high' or 'reasonable':

- ***EU FCM rules,***
- ***national (EU Member States),***
- ***national (third countries).***

If you have replied by 'very high' or 'high', please briefly describe the most burdensome costs and their sources.

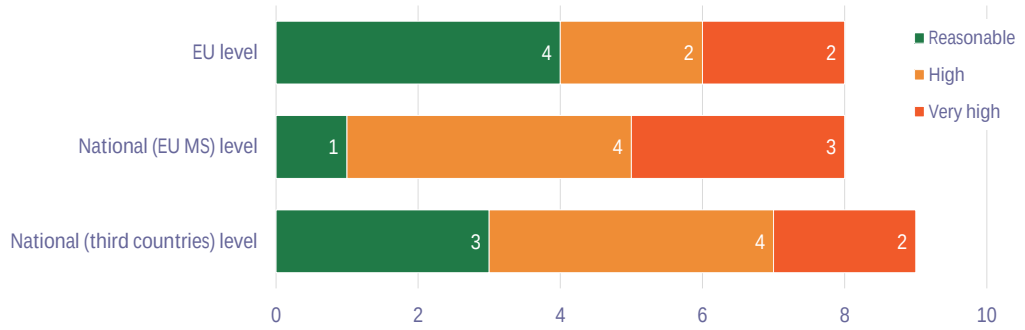
Assessment of compliance costs

Almost all businesses have indicated an answer to this question, although not all its elements were addressed equally.

Fifteen businesses[79] have assessed compliance costs choosing among: 'very high', 'high' and 'reasonable' but also adding new categories: 'considerable', 'relatively high' and 'high to very high'. However, only nine businesses have related their assessments of costs to a particular level at which the rules have been introduced, thus fully replying to the question:

- EU level: very high - 2 businesses; high - 2 businesses; reasonable - 4 businesses;
- national level (EU Member States): very high - 3 businesses; high - 4 businesses; reasonable - 1 business;
- national level (third countries) very high - 2 businesses; high - 4 businesses; reasonable - 3 businesses.

Graph 3: Businesses' assessment of compliance costs by level of the cost source



* Not all 22 businesses participating in the survey have attributed their assessments to all three levels of cost source.

This distribution of answers shows that the compliance costs for businesses generated at national level (both at EU Member States' and third countries' level) are *perceived* by businesses as mostly 'very high' or 'high', while opinions as regards costs generated at EU level are divided between 'very high', on the one hand, and 'high' and 'reasonable', on the other.

Furthermore, seven businesses have only generally assessed compliance costs without relating them to a particular level at which the rules were established. These businesses assess compliance costs as follows:

[79] The figures, as regards assessment of compliance costs, include the assessments made by all three categories of businesses.

- very high - 1 business
- (relatively) high - 1 business
- high – 1 business
- high to very high - 1 business
- considerable - 2 businesses
- reasonable - 1 business

As a general trend, assessments of compliance costs as 'high' or 'very high' were given mostly by businesses (manufacturers and/or processors) whose FCM is currently not covered by EU specific measures, as well as by businesses (distributors) and businesses (directly using FCM products).

Sources of compliance costs

Some businesses have not specified the main sources of compliance costs. As a common trend among businesses who did reply, compliance costs have two main sources:

- costs associated with petitioning (including the preparatory laboratory testing work and preparation of petitioning documentation); the multiplication of petitioning procedures for the same substance under differing national legislations and hence the multiplication of costs are quoted as a key burden here too, and
- costs associated with the provision of staff with adequate knowledge and experience in both scientific research and relevant FCM legal requirements.

Individual businesses also report on the following sources generating compliance costs:

- costs related to maintenance of traceability documents (GMP-related documentation, DoC, etc)
- costs related to exchange of info in the supply chain.

To this question, one could associate observations made by businesses under other questions: operating on different markets implies compliance with multiple-source requirements which in turn involves the opening of parallel process lines (parallel supply chains) adapted to the relevant set of requirements. This multiplies costs by creating competitive disadvantages for businesses while also increasing prices of food products for the end consumer.

Businesses (distributors)

EuroCommerce:
'... Very high costs are linked to the need to re-label, or even develop multiple parallel supply chains for the same (food) product due to different national requirement.'

Businesses (directly using FCM products)

FoodDrinkEurope:

'The major areas of costs are likely to be:
- Internal resources needed to liaise with suppliers, review and validate documents internally
- Analytical testing (migration, NIAS screening…)
- External lawyer fees in case of doubt in the interpretation of a specific provision
- Compliance with specific measures that are disproportionate (i.e.BPA) is of high cost.'

Conclusions: Compliance costs generated at national level (both at EU Member State and third country level) are *perceived* by businesses as mostly 'very high' or 'high', while opinions as regards costs generated at EU level are divided between, on the one hand, 'very high' and 'high', and, 'reasonable' on the other. However, this observation is based on answers indicated by less than the majority of businesses participating in the survey. Nevertheless, *regardless of the level of governance generating the compliance costs*, the majority of businesses participating in the survey (including distributors and food makers), generally consider compliance costs in the range between 'high' and 'very high'. As a general trend, assessments of compliance costs as 'high' or 'very high' were given mostly by businesses (manufacturers and/or processors) whose FCM is currently not covered by EU specific measures, as well as by businesses (distributors) and businesses (directly using FCM products).

The main sources of compliance costs are associated with petitioning (including testing laboratory work), ensuring adequate staffing as well as relevant documentation in the supply chain (such as DoCs and supporting documents).

Q 25 (addressed to businesses)

> ***If possible, please also express the 'compliance costs', generated by EU and national FCM rules (including the costs for authorisation of substances at EU and national level), as a percentage of your relevant members' annual turnover.***
>
> ***Please specify what percentage of the 'compliance costs' (declared above) is generated by:***
>
> ***- EU FCM rules,***
> ***- national rules (EU Member States),***
> ***- national rules (third countries).***
>
> ***Please also briefly describe the different effects of 'compliance costs' on large-, medium-, small- and micro-sized enterprises.***

The large majority of **businesses** have not indicated information under this question; as a result, no conclusion could be drawn as regards the share of compliance costs in the annual turnover of businesses participating in the survey.

However, some businesses have made comments on the effects of compliance costs on SMEs in the sense that in-house analytical equipment, expertise and preparation for petitioning require resources that SMEs could not always afford.

Q 26 (addressed to competent authorities)

> ***From your perspective, how would you assess the 'enforcement costs' generated by current EU FCM rules?***
>
> ***Please select between 'very high', 'high' or 'reasonable'.***
>
> ***If you have replied by 'very high' or 'high', please briefly describe the most burdensome costs and their sources. If possible, please also express 'enforcement costs' in budgetary terms.***

Assessment of enforcement costs

All Member States have indicated an answer under this question but some of them have not really assessed enforcement costs.

Member States are not united when asked to assess enforcement costs. More than half have assessed enforcement costs as 'reasonable'. Six competent authorities assessed costs as 'very high', three - as 'high'.

In three cases, Member States have indicated more than one option. This reflects the fact that, for these countries, the costs vary depending on the nature of enforcement activities carried out. For example, costs could be assessed as 'very high' when controls are based on sampling and testing, and 'reasonable' when controls are based on controls of compliance documentation.

Member States, estimating enforcement costs as 'very high' or 'high' (but also as 'reasonable') almost unanimously report that the main source of enforcement costs are safety assessment activities, such as sampling (including preservation of samples), testing, provision and maintenance of laboratory equipment, usage of accredited laboratories at home and in other MS etc.

Individual Member States have outlined challenges such as:

- those related to staff (such as ensuring enforcement officers with knowledge and experience in relevant law and research),
- the costs related to the on-the-spot inspections themselves (and after-inspection activities), and
- other (mostly administrative and non-specified) costs.

Only one Member State has observed that enforcement costs are higher for FCMs not covered by specific measures at EU level. In addition, the German Länder report that costs depend very much on the number of businesses operating in the relevant Land.

It is impossible to assess what the FCM-related enforcement costs represent in budgetary terms because the submitted data is not complete. Some Member States also report that the costs related to enforcement of relevant FCM rules are part of the costs related to food

safety, in general. The Danish Food and veterinary administration reports that part of the costs generated by the approximately 600 annual inspections performed by the Danish Food and Veterinary Administration are covered by business operators.

Conclusions: The assessment of competent authorities as regards enforcement costs range from 'reasonable' to 'very high', with 'reasonable' indicated by more than the half of the Member States. Safety assessment activities are considered as main source of enforcement costs mainly by MS assessing costs as 'high' or 'very high'. Other important sources of enforcement costs are related to staffing, the very inspections, as well as general administrative costs.

3.2.3. Assessment of compliance and enforcement (control) activities and cooperation between relevant stakeholders (checking Effectiveness/Efficiency/Utility)

Q 27 (addressed to businesses and competent authorities)

To which of the following statements, regarding the intensity of controls by competent national authorities, would your sector/competent authority subscribe:

1. no official controls are carried out,
2. official controls are carried out from time to time on a routine basis,
3. extensive and regular official controls are carried out?

(For businesses only): Are your members witnessing differences in terms of intensity of controls from one Member State to another? Please, reply by 'yes' or 'no'.

Businesses (manufacturers and/or processors)

Almost all businesses have replied to this question.

For the majority of businesses participating in the survey (excluding distributors who do not have available information), official controls on the compliance of the relevant FCM are carried out by the enforcement authorities 'from time to time on a routine basis'. The latter observation coincides with what the majority of Member States report on their control activities, although the ratio differs.

Businesses also report on lack of controls for the relevant food contact materials in some Member States. Individual business stakeholders report that the controls for the particular FCM that they manufacture/process are 'extensive and carried out on a regular basis', and this is only true for some Member States.

Several businesses have not indicated whether their members were witnessing differences in terms of intensity of controls from one Member State to another. The majority of businesses, participating in the survey, are of the opinion that differences in Member States' control approaches for one and the same FCM do exist.

Businesses (distributors)

EuroCommerce:

'no overview available'

Competent authorities

All Member States have replied to this question.

Half of the Member States perceive official controls as 'carried out from time to time on a routine basis'. The other half reports that controls are 'extensive and regular'.

Conclusion: For the majority of businesses and half of competent authorities, controls are carried out 'from time to time on a routine basis' thus sharing a common perception as regards the intensity of controls. This assessment is not conditional upon the availability or lack of specific measures. The majority of businesses participating in the survey are of the opinion that differences in the intensity of controls for one and the same FCM do exist across the EU. Some businesses report specifically on the fact that in some Member State the relevant FCM are not controlled at all, but without giving concrete examples.

Q 28 (addressed to businesses, competent authorities, and Commission)

> ***How would you assess your cooperation with Member States' competent authorities (alternatively businesses) when it comes to controls of compliance with the EU FCM rules?***
>
> ***Please choose between 'most often good' or 'most often problematic'.***
>
> ***If you have replied with 'most often problematic', please briefly describe the main cooperation challenges.***

Both **Member States** and **businesses (manufacturers and/or processors)** report, almost unanimously, that their cooperation with each other is 'most often good' as far as official controls are concerned.

For **businesses (manufacturers and/or processors)**[80], problems in cooperation often arise when competent authorities come up with different requirements (also interpretations of rules) in the different Member States. Businesses also tend to refer to the need of better training of enforcement officials.

For Member States, problems, wherever encountered, are mostly related to incomplete compliance documentation submitted by businesses. Under this and other questions competent authorities point to insufficient knowledge demonstrated by business operators as regards ensuring compliance (knowledge of applicable rules, preparation of reliable compliance documentation (such as DoCs and supporting documents), etc.

Under this, but also under other questions, individual competent authorities point to a problem pertinent to enforcement: business FCM operators are difficult to identify.

[80] Businesses (distributors), EuroCommerce: 'no conclusive input'.

European Commission (Food and Veterinary Office):

> 'Concerning official control of food contact materials, of DG SANTE (Directorate Health and food audit and analysis, ex-Food and veterinary office)' assessed the official control on food contact material in 18 MS form 2007 to 2010 to evaluate the implementation of relevant EU legislation. It visited central as well as local competent authorities, official laboratories, manufacturers and importers as well as users of food contact material (e.g. food processors). SANTE found[81] that there were generally well established risk-based official controls at manufacturing level, but less intensive controls at food processors.
>
> Taking into account the period of controls, implementation had only recently started and further efforts were found to be needed to develop the control system (e.g. elaboration of specific guidelines, upgrading of laboratories, specific training etc.). Not all control staff was sufficiently trained on specific issues (e.g. declaration of compliance, traceability systems and good manufacturing practice). Moreover, competences within authorities were not sufficiently clear, resulting in the lack or overlap of official controls. The Member States that were visited provided action plans in response to the recommendations, which in turn were followed up. This was complemented by training session organised under the 'Better training for safer food[82]' programme in 2007, 2010 and 2012/13[83]' [84].

Conclusions: Both Member States and businesses (manufacturers and/or processors) report, almost unanimously, that their cooperation with each other is 'most often good' as far as official controls are concerned. For businesses, problems in cooperation often arise when competent authorities come up with different requirements (also interpretations of rules) in the different Member States. Businesses also tend to refer to the need of better training of enforcement officials. For Member States, problems, wherever encountered, are mostly related to incomplete compliance documentation submitted by businesses. Under this and other questions competent authorities point to insufficient knowledge demonstrated by business operators as regards ensuring compliance (knowledge of applicable rules, preparation of reliable compliance documentation (such as DoCs and supporting documents), etc. Under this, but also under other questions, individual competent authorities point to a problem pertinent to enforcement: business FCM operators are difficult to identify.

Q 29 (addressed to Commission)

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[81] European Commission, Directorate General for Health and Food Safety, Audit Reports, 2016.
[82] 'Better Training for Safer Food' is a Commission initiative aimed at organising a Community (EU) training strategy in the areas of food law, feed law, animal health and animal welfare rules, as well as plant health rules.
[83] European Commission, Directorate General for Health and Consumers, Better training for safer food, 2014.
[84] Concerning FVO's activities, and in particular audits and reporting, see European Parliament, Policy Department A Economic and Scientific Policy study Food safety situation in Ireland and overview of the Food and Veterinary Office, 2015, p. 25-28.

In your opinion, are the sanctions (under Article 25 of Regulation (EC) No 1935/2004) laid down by Member States effective, proportionate and dissuasive enough to make businesses respect EU FCM rules?

Please explain briefly.

Commission - n/a

One **researcher** (under another question) makes a comment that better tools for enforcement are necessary. It is suggested that fines should be issued for non-compliant companies.

Consumers and food contact materials. Assessment of cooperation between consumers and relevant stakeholders (checking Effectiveness/Utility)

Q 30 (addressed to businesses and consumers)

When it comes to food contact materials, do your members cooperate with Member States' competent FCM authorities and on what occasions?

How would you assess you cooperation with Member States' competent authorities? Please choose between 'most often good' and 'most often problematic'.

If you have replied with 'most often problematic', please briefly describe the main cooperation challenges. Please, indicate, if your answer would vary from one MS to another.

Businesses (directly using FCM products) report on the following occasions on which they cooperate with Member States' authorities:

FoodDrinkEurope:
'through nationals trade associations to provide industry input on new texts and to understand authorities' interpretation/implementation of regulatory provisions. The cooperation challenges were assessed as: most often good.'

Consumers

Both consumer organisations report that they cooperate with competent authorities and give examples. Consumer organisations are active in sharing test results with competent authorities.

DCC (country-specific case):
'we advise (competent authorities) of our tests, and we have continued dialogue with them, especially before and after publishing our findings'.

Cooperation is assessed by DCC as 'most often good'.

ANEC:

'when testing food contact materials, national consumer organisations[85] often take contact with relevant authorities, if consumer concerns are experienced by national consumer organisations. For example, Altroconsumo signalled to the Ministry of economy and health, the test results asking to oblige producers to pre-treat the products before putting them on the market to reduce the migration during the first uses and that they inform on the packaging of the washing indications. Similar concerns on the release of these materials to baked food were resulted from controls in France in 2005 and in Germany in 2006.'

ANEC has not assessed cooperation, pointing out that their members (national consumer organisations) 'might wish to report their experiences'.

Conclusions: Businesses (directly using FCM products) come in contact with competent authorities through national trade associations to provide industry input on new texts and to understand authorities' interpretation/implementation of regulatory provisions. Cooperation is assessed as 'most often good'. Consumer organisations cooperate with MS' competent authorities on various occasions, and mostly as regards FCM safety tests done by consumer organisations themselves. Wherever indicated, cooperation is assessed as 'most often good'.

Q 31 and Q 32 - to be considered together

Q 31 (addressed to competent authorities)

Do you enter in contact with consumers and on what occasions?

Please describe briefly.

Two Member States have not answered this question.

The large majority of Member States report that they have contacts with consumers as regards food contact materials. Both competent authorities and consumers initiate these contacts.

Competent authorities' proactive behaviour takes the following forms:

- authorities inform consumers on, for example, non-compliant products on the market, and, their possible withdrawal, on substances attracting public attention e.g. BPA etc;
- authorities answer to citizens' enquiries, complaints, and submitted information;
- authorities consult consumers' organisations and/or involve them in their legislative work as regards FCMs.

Consumers proactive behaviour takes the following forms:

- consumers are looking for information by submitting questions, enquiries to competent authorities;

[85] ANEC has submitted information on FCM safety tests conducted by their member organisations: ASI Consumer Council (Austria), Test-Aankoop/Test-Achats (Belgium), Forbrugerradet (Denmark), Altroconsumo and Nanodiagnostics (Italy), Stiftung Warentest (Germany).

- consumers complain about FCM products;
- consumers inform the authorities on FCM issues (confirmed by consumers under Q 30).

It is rare, however, that Member States witness the whole set of cooperation activities identified above – the cooperation models (combination) differ from one MS to another.

Based on the submitted data, competent authorities and consumers most often enter in contact with each other on the following occasions:

- consumers ask for information on FCMs (via questions, enquiries etc) and public authorities provide the relevant information;
- consumers complain and competent authorities respond to their complaints.

The channels of communication most often quoted are: e-mails, phone calls, e-mails, Facebook, and competent authorities' dedicated interactive platforms/websites.

Q 32 (addressed to competent authorities)

How would you assess your cooperation with consumers? Please choose between 'most often good' or 'most often problematic'.

If you have replied with 'most often problematic', please briefly describe the main cooperation challenges.

Almost all Member States have indicated an answer to this question - mostly those who do not enter in contacts with consumers.

The large majority of competent authorities assess their cooperation with consumers and their organisations as 'most often good', which is confirmed done by the Danish Consumer Council under Q 30.

Conclusion for Q 31 and Q 32:

Based on the submitted data, competent authorities and consumers most often enter in contact with each other on the following occasions:

- consumers ask for information on FCMs (via questions, enquiries etc) and public authorities provide the relevant information;
- consumers complain and competent authorities respond to their complaints.

The large majority of competent authorities assess their cooperation with consumers and their organisations as 'most often good' which is confirmed by consumers under Q 30.

Q 33 (addressed to businesses and consumers)

Based on your members' contacts with costumers/consumers, please briefly describe the perception of customers/consumers as regards safety: do they trust FCM safety?

Please reply by 'yes' or 'no'.

Please also indicate which are the articles and materials (respectively the products manufactured using FCMs, e.g. packaging, kitchenware and utensils, etc.) that costumers/consumers trust and/or mistrust.

businesses (distributors)

EuroCommerce:

'Yes, consumers still trust FCM, however once an issue is taken up by the media - such as was the case in France on BPA - this lead to suspicion from consumers on this substance. On the whole, our members don't get a lot of questions from consumers regarding FCM. Another example is press coverage regarding the investigations of German NGO's like Food watch or Stiftung Warentest on mineral oils. Subsequently the issue was heavily discussed by consumers, also on social media.

Consumers mistrust those articles where there is national legislation such as the baby bottles in France.
In general, consumers trust kitchenware, utensils, food preparation articles (kitchen aids etc)';

Businesses (directly using FCM products)

Food Drink Europe:

'It was indicated that the level of trust varies. The perception of consumers as regards trust in FCM safety depends on social and cultural level; additionally, it was noted that media and consumer associations play an important role on this; myths spreading from time to time create doubts on the safety of materials (ex: plastics in general, PET, PS) or specific components (BPA< endocrine disruptors, or mineral oils in recycled paper and board). Members indicate that there is a risk of losing consumers' confidence'.

Consumers

Danish Consumers' Council:

'Yes and No. Mostly yes but also a small no - in Denmark there have been a lot of testing of FCMs and the finding of many unregulated substances have shaken the public's trust in the safety of the FCMs. In Denmark we have even set up national guidelines and voluntary limit values on certain substances in FCMs.

Pizza boxes, microwave popcorn packaging, paper packaging in general, cans, metal packaging'.

ANEC :

'The question cannot be answered with certainty in absence of research. However, it can be assumed that test results e.g. by national consumer organisations demonstrating food contamination originating from FCM not covered by EU legislation will not enhance the confidence in the European regulatory system and will lead to questioning the safety of products in the internal market'.

Conclusion: The submitted data does not allow for a clear trend to be identified.

However, these observations correlate/resonate with observations of competent authorities and businesses as regards the implementation of EU FCM rules and the achievement of the 'safety objective': FCMs that are not covered with specific measures at EU level are considered a risk of lower safety and hence, consumers' mistrust.

Q 34 (addressed to businesses and consumers)

Do consumers recognise FCM indications on labels such as e.g. the symbol in Annex II to Regulation (EC) No 1935/2004?

Please chose between 'most often 'yes' or 'most often 'no'.

Businesses (distributors)

EuroCommerce:
'no feedback'

Businesses directly using FCM products)

FoodDrinkEurope:
'Most often no. Our members are selling packed food where the FCM symbol is not required on a pack; several recent studies showed that consumers feel rather confused by the exponential increase of symbols and labels. Especially younger consumers know little about symbols and labels. Consumers tend to take food contact appropriateness for granted for any item suitable for food contact, even sold in isolation of food'.

Consumers

Danish Consumers' Council:
'Most often yes. We have not done any surveys but we believe that a lot of consumers have seen the label, and a fewer understand what it actually means.'

ANEC:
'The FCM indications on labels are presumably largely unknown'.

Conclusion: The submitted data does not allow for clear conclusions to be drawn. However, the comments refer to problems as regards FCM labelling and how recognisable they are for consumers.

3.2.4. General implementation assessment

3.2.4.1. Assessment of the achievement of the objectives of the EU FCM policy. Key implementation challenges (checking Effectiveness)

Q 35 (addressed to businesses, competent authorities, Commission, EFSA, consumers, health/environmental NGOs)

From your perspective, is the implementation of current EU FCM rules ensuring:

- the safety of FCM, and
- the effective functioning of the internal market?

Please briefly describe the main implementation challenges.

Businesses (manufacturers and/or processors)

All business stakeholders (but one) have indicated an answer under this question. However, not all of them have fully addressed all its elements. Individual businesses have not clearly expressed their assessments and only made comments are regards main implementation challenges.

– **on 'effective functioning of the internal market'**

Half of the businesses, participating in the survey, have indicated a negative answer. The other half replies by 'yes' or gives no clear assessment.

However, 'yes' and 'no' responses tend to be conditional: the assessment is subject to the availability or lack of EU specific measures for the relevant FCM(s). Thus, according to the majority of businesses, participating in the survey, the functioning of the internal market is (or at least is more) effective for FCMs for which specific measures at EU level have been adopted and implemented, and is negatively affected for FCMs for which no such measures were adopted.

businesses (distributors)

EuroCommerce:
'No, various examples exist of national initiatives creating single market barriers'

businesses directly using FCM products

FoodDrinkEurope:

'Challenges regarding the internal market
- The implementation of harmonised measures is so slow that Member States develop National Regulations (i.e. BPA) that create distortion of internal market. Proper and timely action of the EC on measures infringing EU law is required to prevent de-harmonisation.'

– **on safety**

The majority of businesses, participating in the survey, have indicated a positive answer thus reporting that the implementation of current EU FCM rules ensures safety of the relevant FCM. The minority of businesses replies by 'no' or gives no clear assessment.

Unlike effective functioning of the internal market, safety of (the relevant) FCMs is not perceived as depending on the existence of EU specific measures. Some businesses specify that the existing legal requirements (as laid down in the relevant

EU regulations) as well as self-regulation/sector-specific guidelines are enough to ensure FCM safety.

Businesses (distributors)

EuroCommerce:
'Regarding the safety of the material: yes, according to currently available scientific opinions and methods of analysis. If new scientific information is available the FCM should be amended.'

Businesses (directly using FCM products)

FoodDrinkEurope
'Challenges regarding food safety assessment
- Obtaining sufficient information from supplier in their DoC, Low level of knowledge of available regulatory and non-regulatory texts by suppliers to prove safety of materials (harmonised and especially for non-harmonised materials). Risk assessment of NIAS (non-intentionally added substances): although the Plastic Regulation (10/2011) defines this as a mandatory requirement, it is very often not done by the supplier.'

Competent authorities:

Although all competent authorities (but one) have indicated an answer under this question, not all of them have fully addressed all its elements: like businesses, some Member States have not clearly expressed their assessments and only made comments are regards main implementation challenges.

- **on 'effective functioning of the internal market'**

Half of the competent authorities, participating in the survey, have indicated a positive answer, the other half replying by 'no' or giving no clear assessment.

However, both 'yes' and 'no' answers tend to be conditional: *like* businesses, the assessment is subject to the availability or lack of EU specific measures for the relevant FCM. Thus, according to the majority of competent authorities, participating in the survey, the functioning of the internal market is (or at least is more) effective for FCMs for which specific measures at EU level have been adopted and implemented, and is negatively affected for FCMs for which no such measures were adopted.

- **on safety**

The majority of competent authorities, participating in the survey, have indicated a positive answer thus reporting that the implementation of current EU FCM rules ensures safety of the relevant FCM. The rest replies by 'no' or gives no clear assessment.

Unlike businesses, the majority of Member States consider that FCM safety is also subject to the availability or lack of EU specific measures for the relevant FCM, thus reporting that FCM safety is (or at least is better) ensured for FCMs for which EU specific measures have been adopted and implemented, and is difficult to be ensured for FCMs for which EU specific measures have not been adopted.

Both observations - on market and safety - are further endorsed by the comments of Member States who have not clearly expressed their assessments.

Commission: n/a

EFSA also tends to make a distinction between FCMs covered by specific measures at EU level and uncovered FCMs when it comes to FCM safety and functioning of the internal market, stating that:

- **on 'effective functioning of the internal market'**

'when there is a lack of harmonisation for safety assessment, this impairs mutual recognition'.

- **on safety**

'As regards EU regulated materials and articles such as plastics, safety is ensured for the evaluated substances (e.g. monomers and additives) although some aspects need to be strengthened to provide a higher level of protection for infant and toddlers (see EFSA's recently adopted CEF Panel opinion on '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'. Other substances still for plastics, e.g. colorant, solvents, etc. are not evaluated by EFSA. The evaluation of NIAS remains a challenge. The evaluation of the safety of other materials lays on national rules and/or industries self-assessment'.

Consumers

Like Member States' competent authorities, consumers have also put FCM safety subject to the availability/lack of EU specific measures.

DCC:

'we question the safety of FCMs, when a lot is not regulated when the combination effects are not considered, and when the chemicals regulations at the EU level is divided up into different legislation, each not looking at what is going on in the others. One example is phthalates being banned in toys, but not in many other products and FCMs.'

Health/environmental NGOs

ChemTrust considers that the implementation of current FCM rules does not ensure FCM safety and effective functioning of the internal market and also relates these results to the lack of EU specific measures for some FCMs.

Implementation challenges

Next to 'lack of EU specific measures for the relevant FCM', the implementation challenges most often quoted by **businesses (all three categories)** are (listed in quotation-frequency order):

- compliance is burdensome due to divergent national rules (including standardised analytical/test methods/procedure for petitioning etc) or lack of rules;
- controls of imports from third countries are problematic (not sufficient);
- the application of the mutual recognition principle varies across MSs which disturbs the functioning of the internal market - confirms the findings under several questions.

With their answers under this question businesses confirm the observations and trends outlined under other questions.

Other implementation challenges quoted by individual **businesses (all three categories)**:

- different models of controls among MS create the risk of de facto setting new legislation for FCMs which are currently covered by EU specific measures;
- problems related to the exchange of info in the supply chain due to problems with compliance documentation/lack of knowledge of rules/confusion even with the guidance/etc.;
- risk assessment of NIAS (non-intentionally added substances);
- the implementation of harmonised measures is so slow that Member States develop national regulations (i.e. BPA) that create distortion of the internal market. Proper and timely action of the EC on measures infringing EU law is required to prevent de-harmonisation;
- unfair competition among the food contact materials themselves;

Next to 'lack of EU specific measures for the relevant FCM' the implementation challenges most often quoted by **competent authorities** are:

- challenges as regards compliance by businesses and relevant supporting documents exchanged in the supply chain due to problems with compliance documentation/lack of knowledge of rules/confusion even with the guidance

(wherever available) - i.e. without specific measures controls of compliance under Article 3 of Regulation (EC) No 1935/2004[86] are difficult;
- costs for testing FCMs (analytical capabilities);
- challenges as regards controls of FCM imports from third countries;
- problems related to the exchange of info in the supply chain due to problems with compliance documentation/lack of knowledge of rules/confusion even with the guidance/etc.

Other implementation challenges quoted by individual **competent authorities**:

- there are also questions as to the extent to which the current EU FCM rules protect consumers against migration of reaction products and other non-intentionally added substances (NIAS), even for materials such as plastics where specific measures exist;
- several SME-specific comments - often they do not have the capacity to comply with rules, especially if analytical (testing) capacity is required - if an SME does not have proper laboratory and analytical facilities, this work should be outsourced to external laboratories which SMEs often could not afford, and thus compliance with safety requirements could not be ensured.

With their answers under this question competent authorities confirm the observations and trends outlined under other questions.

The implementation challenges quoted by **EFSA** refer to safety (see above under this question):

- '(for plastics) some aspects as regards evaluated substances (e.g. monomers and additives) need to be strengthened to provide a higher level of protection for infant and toddlers (see EFSA's recently adopted CEF Panel opinion on "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")';
- 'the evaluation of NIAS remains a challenge'.

Consumers

DCC:

> 'we question the safety of FCMs, *when a lot is not regulated*, when the combination effects are not considered, and when the chemicals regulations at the EU level is divided up into different legislation, each not looking at what is going on in the others. One example is phthalates being banned in toys, but not in many other products and FCMs'.

ANEC have not indicated a comment.

[86] Establishing the general safety requirements applicable to all FCMs regardless of their status as 'covered' or 'not covered' by specific measures adopted at EU level.

Health/environmental NGOs

ChemTrust considers the following as challenges:

- 'lack of harmonisation
- hard to enforce
- lack of analytical standards to help enforcement'.

Conclusions: for almost half of the stakeholders - participating in the survey and representing businesses, competent authorities, consumers, health/environmental NGO, including EFSA - there is a correlation between the availability/lack of EU specific measures for the relative FCM(s) and the functioning of the internal market for these FCM(s). As regards safety, such correlation is confirmed mainly by competent authorities, consumers and health/environmental NGOs.

Thus the implementation challenge most often quoted by stakeholders is the lack of EU specific measures for the relevant FCM(s). According to the majority of stakeholders participating in the survey, the functioning of the internal market is (or at least is more) effective for FCMs for which specific measures at EU level have been adopted and implemented, and is negatively affected for FCMs for which no such measures were adopted. As regards FCM safety, mainly Member States' competent authorities and consumers consider that safety is (or at least is better) ensured for FCMs for which EU specific measures have been adopted and implemented, and is difficult to be ensured for FCMs for which EU specific measures have not been adopted.

3.2.4.2. Identification and assessment of key economic, social, health and environmental impacts (checking Effectiveness/Utility)

Q 36 (addressed to businesses[87], competent authorities, Commission, EFSA, consumers, health/environmental NGOs)

For each of the following, please, specify (from your perspective) the most important impacts stemming from the implementation of the EU FCM rules and assess them as positive or negative:

- economic impacts - ... (+/-);
- social impacts - ... (+/-),

[87] This question was addressed to all three categories of businesses. However, it was only addressed by businesses (manufacturers and/or processors). Businesses (distributors) have only assessed the suggested impacts as follows: 'economic (neutral), social (neutral) and health/environmental (positive)', without identifying concrete examples. Businesses (using FCM products directly) have not indicated an answer. Therefore, the observations refer to businesses (manufacturers and/or processors), but also take into account the assessment made by business (distributors).
Wherever a reference is made to 'businesses' under this question, this means all 22 business organisations participating in the survey from all three business stakeholders' categories.

- environmental/health impacts - ... (+/-).

Around 20 % of stakeholders have not given answers to this question (i.e. to either of its elements). Some of these stakeholders have signalled difficulties in understanding the question and lack of information to be able to respond.

Thus the key findings presented below are based on the information submitted by around 80 % of the stakeholders participating in the survey. It is worth mentioning that a substantial part of these content-rich responses are not always completed in full: either they address only one of the impacts suggested in the question, or make general comments without attributing clear assessment to some or all of the suggested impacts, or only assess all or some of the impacts without outlining concrete economic, social and environmental impacts etc. In fact, only around 20 % of the stakeholders participating in the survey (or around 25 % of stakeholders indicating content-rich answers) have outlined concrete economic, social and environmental/health impacts and assessed them as positive and/or negative and/or negligible, thus fully replying to the question. It should be noted that several of the latter stakeholders have clearly outlined pertinent environmental impacts separating them from health impacts; therefore, environmental impacts are considered separately from health ones below.

Some stakeholders have qualified the very existence of rules as an (economic) impact *per se*. Such answers were disregarded.

The assessment of impacts done by stakeholders is not subject to a clear distinction between harmonised and non-harmonised FCMs, although some stakeholders (especially among competent authorities) did so, but they are a clear minority. Therefore, the following observations concern, in principle, all FCMs covered by the survey:

Economic impacts

Businesses

Six businesses have not responded to the question. Furthermore, the majority of those who indicated an answer have not fully addressed all the elements of the question.

Overall, the opinions of businesses as regards economic impacts in general are equally divided between positive and negative; one could not say whether positive or negative assessments prevail.

Six businesses have outlined concrete economic impacts and also assessed them thus fully replying to the question. The economic impacts, most often quoted by these businesses, are:

- high/increased compliance costs/ compliance requirements difficult to fulfil - an impact assessed as negative;
- (internal/global) market opportunities (including for SMEs) are created - an impact assessed positively;
- (internal/global) market opportunities (including for SMEs) are lost - an impact assessed negatively.

Individual businesses also report on the following economic impacts:

- less burden for companies operating across Europe (assessed as positive);
- well-designed food packaging can extend shelf-life of food, provide opportunities to reduce food waste and allows food to be transported to remote areas where otherwise supply chain issues would limit food availability (assessed as positive). However, these types of impact are far more social and environmental in nature than economic and they were also taken into account accordingly;
- if EU FCM rules were to be disproportionate and impractical in terms of applying them to food packaging, the cost of food would rise, potentially leading to poor choice of packaging and possible serious negative impact on the EU manufacturers, with the possibility that this would lead to greater off-shore manufacture of food packaging, with greater issues in terms of assuring compliance (assessed as negative), etc. Here, economic impacts are related to possible social and environmental impacts and they were also taken into account accordingly.

Competent authorities

Eleven competent authorities have not responded to this question. Furthermore, the majority of those who indicated an answer have not fully addressed all the elements of the question.

Overall, the Member States (who have indicated an answer under this question) tend to generally assess the economic impacts stemming from the implementation of current EU FCM rules as positive.

Eight competent authorities have outlined concrete economic impacts and also assessed them, thus fully replying to the question.

The economic impacts, most often quoted by competent authorities are:

- (internal/global) market opportunities are created (and hence growth) - an impact assessed positively;
- (internal/global) market opportunities are lost - an impact assessed negatively;
- high/increased compliance costs/compliance requirements are difficult to fulfil - an impact assessed as negative;
- high costs related to enforcement activities - assessed as negative.

Individual competent authorities also report on the following economic impacts:

- a centralised safety assessment (of a substance) reduces costs for both the Member State authorities and the business operators - assessed as positive;
- time-consuming authorisation process may inhibit innovation as well competitiveness of EU producers on the global market - assessed as negative, etc.

Commission - n/a

EFSA - n/a

Consumers - n/a

Health/environmental NGOs
ChemTrust assessed the following economic impacts as negative: 'SMEs (too hard for SMEs to fulfil requirements); (internal market); innovation (no level playing field, lack of regulatory clarity)'.

Social impacts

Social impacts appear to be the more difficult to be outlined and assessed by stakeholders.

Businesses

Eight businesses have not responded to the question. Furthermore, the majority of those who indicated an answer have not fully addressed all the elements of the question.

Businesses tend to generally assess the social impacts stemming from the implementation of current EU FCM rules as positive.

Six businesses (representing FCMs that are currently not covered at EU level) have outlined concrete social impacts and also assessed them thus fully replying to the question.

The social impact, most often quoted by businesses, is:

- (potential) job creation which is unanimously assessed as positive.

Individual businesses also report on the following social impacts:

- public trust in the safety of food sold to consumers is increased - assessed as positive;
- provision of wide range of safe packaged foodstuffs across the whole EU fulfilling consumers' needs and preferences - assessed as positive ;
- image of the relevant sector (conformity) is improved - assessed as positive;
- lack of consumer choice - assessed as negative, etc.

Competent authorities

Twelve competent authorities have not responded to the question. Furthermore, the majority of those who indicated an answer have not fully addressed all the elements of the question.

Overall, the large majority of competent authorities who have indicated an answer under this question, generally assess the social impacts stemming from the implementation of current EU FCM rules as positive.

Six competent authorities have outlined concrete social impacts and also assessed them thus fully replying to the question.

As with businesses, the social impact most often quoted by competent authorities, is:

- (potential) job creation, which is unanimously assessed as positive.

Individual competent authorities also report on the following social impacts:

- safety of FCMs for consumers - assessed as positive (however, it is far more a health impact and was taken into account accordingly);
- confidence in market by consumers - assessed as positive, etc.;

Commission - n/a

EFSA - n/a

Consumers - n/a

Health/environmental NGOs

ChemTrust assessed the following social impacts as negative: 'small food producers are vulnerable'.

Health impacts

Businesses

Seven businesses have not responded to the question. Furthermore, the majority of those who indicated an answer have not fully addressed all the elements of the question.

Overall, the general assessments of businesses (who have indicated an answer under this question) as regards health impacts are divided between positive and negligible whereby positive assessments slightly prevail.

Six businesses have outlined concrete health impacts and also assessed them, thus fully replying to the question.

The health impact, most often quoted by businesses, are:

- protection of human health via risk assessment - assessed as positive

In one case a distinction was made between EU-made FCMs and those imported by third countries - health impacts for products manufactured in the EU were assessed as positive, and health impacts stemming from imported FCMs as negative.

Individual businesses also report on the following health but also social impacts:

- improved traceability - assessed as 'slightly positive';
- long term health improvement would be supported by the provision of compliant, well designed food packaging, but also by the potential to reduce food waste (environmental impact), this would have the effect of keeping food cost to the consumer down (social impact) and providing greater potential to provide more food to a greater number of citizens (social impact), aiding in efforts to reduce malnutrition across a broader range of citizens[88], etc.

Competent authorities

Seven competent authorities have not responded to the question. Furthermore, the majority of those who indicated an answer have not fully addressed all the elements of the question.

Overall, most of the Member States (who have indicated an answer under this question) have generally assessed the health impacts stemming from the implementation of current EU FCM rules as positive.

Eleven competent authorities have outlined concrete health impacts and also assessed them thus fully replying to the question.

The health impact most often quoted by competent authorities is:

- protection of human health via risk assessment - largely assessed as positive

A clear distinction between harmonised and non-harmonised FCMs was made in individual cases only, whereby health impacts for harmonised FCMs were assessed as positive, and for non-harmonised - as negative (but also as positive by one MS).

Commission - n/a

EFSA - n/a

Consumers - n/a

Health/environmental NGOs

ChemTrust assessed the following health impacts as negative: 'consumer health protection'.

[88] The suggested social and environmental impacts were taken into account accordingly.

Environmental impacts

Businesses

Four **businesses** have outlined particular environmental impacts and assessed them.

Overall, the general assessments of businesses as regards environmental impacts are divided between positive and negligible whereby positive assessments slightly prevail.

The environmental impact most often quoted by businesses is:

- reduction of food waste (due to the improved quality of packaging) - assessed as positive

It is also specified (by individual businesses) that products manufactured in the EU have positive environmental impacts, and imported (rarely tested) products - negative ones, and also that the EU FCM policy leads to promotion of more environmental friendly materials in the food sector.

Competent authorities
Six MS have outlined environmental impacts.

Overall, the large majority of Member States have generally assessed the environmental impacts stemming from the implementation of current EU FCM rules as positive.

The environmental impact most often quoted is:

- improved packaging waste management - assessed as positive.

Member States' competent authorities tend to indicate that this improvement is due to the rules on EU FCM on recycled plastics. One MS indicate that the impacts on the environment are positive for EU 'harmonised' FCM rules (e.g. for plastics), and positive and negative for EU non-harmonised FCMs.

Commission - n/a

EFSA - n/a

Consumers - n/a

Health/environmental NGOs

ChemTrust assessed the following environmental impacts as negative: 'environment protection (e.g. use of persistent PFCs /perfluorinated compounds/ in food packaging'.

Conclusions: Given that only some stakeholders to whom this question was addressed have outlined concrete examples of impacts, only overall general assessment of economic, social, health and environmental impacts could be done, as follows:

- *economic impacts* - assessed as positive by Member States, as negative by health/environmental NGOs, and as both positive and negative by businesses;
- *social impacts* - assessed as mainly positive by both businesses and competent authorities and as negative by health/environmental NGOs;
- *health impacts* - assessed as positive by Member States, as negative by health/environmental NGOs and as both positive and negative by businesses;
- *environmental impacts* - assessed as positive by Member States, as negative by health/environmental NGOs and as both positive and negative by businesses.

The following common economic, social, health and environmental impacts were identified by stakeholders:

economic:

for businesses

- high/increased compliance costs/ compliance requirements difficult to fulfil - an impact assessed as negative
- (internal/global) market opportunities (including for SMEs) are created - an impact assessed as positive
- (internal/global) market opportunities (including for SMEs) are lost - an impact assessed as negative

for competent authorities

- (internal/global) market opportunities are created (and hence growth) - an impact assessed as positive
- (internal/global) market opportunities are lost - an impact assessed as negative
- high/increased compliance costs/compliance requirements are difficult for businesses to fulfil - an impact assessed as negative
- high costs related to enforcement activities - assessed as negative

for health/environmental NGOs

- SMEs (too hard for SMEs to fulfil requirements); (internal market); innovation (no level playing field, lack of regulatory clarity)' - assessed as negative

social

for businesses and competent authorities

- (potential) job creation which is unanimously assessed as positive;

for health/environmental NGOs

- ChemTrust assessed the following social impacts as negative: 'small food producers are vulnerable'.

health

for businesses and competent authorities

- protection of human health via risk assessment - assessed as positive

for health/environmental NGOs

- 'consumer health protection' - assessed as negative

environmental

for businesses

- reduction of food waste (mainly due to the improved quality of packaging) - assessed as positive

for competent authorities

- improved packaging waste management - assessed as positive

for health/environmental NGOs

- 'environment protection (e.g. use of persistent PFCs/perfluorinated compounds/in food packaging'.

3.2.4.3. The EU FCM policy and other EU policies (coherence/complementarity)

Q 37 (addressed to businesses, competent authorities, Commission, EFSA, consumers, health/environmental NGOs, researchers)

From your perspective, do the EU FCM rules support and usefully supplement related EU policies: for example, are the EU FCM rules supporting or preventing the reduction of food waste, proper management of waste, positively or negatively affecting consumer policies or health policies, etc. (if relevant, please, identify and comment on other policy examples)[89]?

Please reply by 'yes' or 'no'.

[89] It should be noted that the examples given under this question were tailored to the category of stakeholder to which the question was put.

If you have replied by 'no', please briefly describe why.

Businesses (manufacturers and/or processors)

Almost all businesses have indicated an answer under this question. The majority of those who have given an answer considered that the EU FCM rules support and usefully supplement related EU policies, and especially those given as examples. Both 'yes' and 'no' answers tend to be supplemented by explanations on the link between FCM and other EU policies.

Several comments (mostly by businesses manufacturers and/or processors) point out that:

- the existence of EU specific measures leads to reduction of food waste while the absence of EU specific measures (and excessive use of the precautionary principle) counts for food waste increase, for example:
  - BPA in coatings (extending food shelf-life) is not harmonised at EU level (with bans introduced in some Member States) and thus leads to reduction of the shelf-life of packaged food and increases food waste;
  - **Businesses (distributors)**, EuroCommerce: '... the lack of harmonised rules goes against the single market regulation. Non harmonised rules can contribute to food waste: if food contact products need to be taken out of the stores, due to consumers being uncertain as NGOs classify a product having a health risk, this contributes to food waste.'
- other policies affect the EU FCM policy, as follows (resonating with observations made under other questions):
  - other policies do not support the FCM policy sufficiently - e.g. REACH, Ecodesign, CLP (classification, labelling and packaging), or
  - when awareness in one policy area has increased, this has in turn influenced the discussions on FCM policy: e.g. awareness has risen in terms of health policies which influenced the discussions on FCM policies.
- businesses refer to the circular economy package and recycling, however, no clear trend could be outlined. In some businesses' words:
  - what appears to be beneficial from the viewpoint of the circular economy, has the potential to be detrimental to consumer safety (a most recent example is the discussion around the use of recycled paper & board as food packaging);
  - while the EU is rightfully aiming at reducing packaging waste and building the green single market (in the context of the circular economy), it would be important to assess in a combined manner the environmental performance

of FCMs (e.g. endless recyclability), their ability to limit or prevent food waste (e.g. shelf-life in relation to different food contact materials), together with the level of protection they offer to the consumer (e.g. leaching behaviour). Horizontal policies capable of assessing and taking into account the overall function of food contact materials would be preferable to fragmented policies that are disconnected from the overall function and look only at individual aspects and phases of the FCM life cycle.

- **Businesses (directly using FCM products)**, FoodDrinkEurope: 'Packaging waste directive encourages more and more recycling, but EU rules for FCM recycling are not fully addressed (only plastics addressed nothing on other materials such as paper and board).'

Competent authorities

Individual Member States have not indicated an answer under this question. The majority of those who have given an answer considered that the EU FCM rules support and usefully supplement related EU policies, and especially those given as examples. Less than the majority of MS participating in the survey have added comments to their assessments.

As with businesses, the comments point out that the existence of specific measures adopted at EU level leads to reduction of food waste while the absence of EU specific measures (and excessive use of the precautionary principle) counts for food waste increase. EU specific measures (specifically for plastics) e also considered as having a slightly positive effect on health;

Commission: n/a

EFSA:

'The EFSA CEF panel evaluates substances prior to their authorisation by the European commission using pre-agreed criteria which may directly or indirectly impact other EU policies'.

Consumers

Consumers' organisations are unanimous in their assessment that the EU FCM rules do not support and usefully supplement related EU policies, and especially those given as examples.

DCC:

'There is a need for horizontal legislation of chemicals in consumer goods; substances banned in toys should not be allowed in FCMs and vice versa. FCMs should be designed in a way so that they can be "recycled" into new FCMs (as is done with cans and bottles here in Denmark). This means that the number of chemicals "allowed" from the beginning should be reduced to a minimum'.

ANEC:

'No. It should be supplementing these policies but in absence of transparency on materials and substances used it is difficult to ensure this objective; The Commission 2012 Roadmap for non-plastics materials in contact with food already referred to criticism by MSs, industry and the European Parliament on the lack of EU specific legislation for materials other than plastics in light of food scares originating from packaging'.

Health/environmental NGOs

ChemTrust:

'First, the inadequacy of FCM rules has a negative effect on the circular economy. The EU as binding targets for recycling packaging, yet is not properly controlling the chemical contents of this packaging. This is not consistent with the aim to achieve clean material cycles; Second, in addition, the lack of oversight of processes recycling paper and card into food packaging (in contract to plastics recycling processes) fails to protect human health and also creates a major risk of undermining public confidence in the entire circular economy approach; third, EU Consumers believe that regulations are in place to protect them, and they view this as an important part of the role of the EU. Where this is not the case – for example in the FCM area – this risks further undermining public confidence in the EU. It will also beg the question as to why this area is so poorly regulated – EU Commission incompetence, industry lobbying?'

Researchers:

Not all researches have indicated an answer; those who did so indicated both 'yes' and 'no' answers. However, researchers' comments under this question do not allow for a clear trend to be outlined.

Conclusions: At least half of the stakeholders participating in the survey consider that the EU FCM rules support and usefully supplement related EU policies. Some businesses (mostly manufacturers and/or processors) also consider that other policies affect the FCM policy. Consumers' organisations and health/environmental NGOs are unanimous in their assessment that the EU FCM rules do not support and usefully supplement related EU policies.

Based on comments of some businesses (mostly business (manufacturers and/or processors and business (distributors)) and Member States the following trend emerges: the existence of specific measures adopted at EU level leads to reduction of food waste while the absence of EU specific measures (and excessive use of the precautionary principle) counts for food waste increase. This opinion, however, is expressed by a minority of the stakeholders participating in the survey. Other links between the EU FCM policy and other policies are made by respondents on an individual basis.

3.2.4.4. Assessment of the added value of the EU FCM policy

Q 38 (addressed to businesses, competent authorities, Commission, EFSA, consumers, health/environmental NGOs)

Could the results from the implementation of EU FCM rules that you have identified above, be equally or better achieved at Member State level?

Please, reply by 'yes' or 'no', and, in both cases, explain why.

Stakeholders (across most categories) almost unanimously state that the results of the implementation of EU FCM rules could not be equally or better achieved at Member State level. The implementation of current EU FCM rules adds value to the effective functioning of the internal market and food safety, and thus this EU policy has no alternative at national level. However, specific (and, as a general rule, divergent) measures adopted at national level (for the FCM currently not covered by EU specific measures) are perceived by all categories of stakeholders as distorting the effective functioning of the internal market, if and when the mutual recognition principle is not uniformly implemented by MS. Furthermore, national measures do not necessarily achieve food safety.

The opinion of EFSA illustrates this conclusion best:

> 'Although the question is outside EFSA's remit, from the risk assessment point of view one could argue that as in most cases, harmonisation functions best at EU level but it can also work at MS **when there are commonly agreed standards and mutual recognition**'.

Furthermore, the existence of divergent measures adopted at national level inhibits the capacity of Member States' competent authorities to control compliance which ultimately leads to economic, social and health impacts as mentioned above.

Q 39 (addressed to businesses, competent authorities, Commission, EFSA, consumers, health/environmental NGOs, researchers)

If you consider it important, please comment on issues which couldn't be raised answering the above questions and also express your recommendations for improvement of current EU FCM rules and their implementation.

The recommendations are presented in the next part of the study.

4. Identification of major implementation problems and stakeholders' key recommendations. Final implementation assessment

As revealed in the previous chapter, almost all categories of stakeholders have pointed to problems related to the current EU FCM legal framework, on the one hand, and its implementation, on the other.

Based on stakeholders' responses, this part of the European Implementation Assessment study summarises the main implementation problems identified by stakeholders. In parallel, stakeholders' key recommendations are outlined. Finally, the current EU FCM rules and their implementation are assessed against the set of key assessment criteria for evaluations - relevance, coherence, EU added value, effectiveness and efficiency - but also against two additional criteria pertinent to the EU FCM policy: complementarity and utility.

4.1. Problems inherent to the current EU FCM rules. Stakeholders' key recommendations

4.1.1. Problems inherent to the current EU FCM rules

The collected data shows that for a large majority of stakeholders (across most categories) the current EU FCM legal framework is not complete: **specific measures at EU level for 13 out of the 17 FCMs listed in Annex I to Regulation (EC) No 1935/2004 have not yet been adopted.**

The adoption of such measures lies with the European Commission which, under Article 5 (1) of framework Regulation (EC) No 1935/2004, may adopt such measures[90] but is not obliged to do so. Specific measures are implementing measures *per se*. Thus, the availability or the absence of implementing measures for some of the FCMs[91] directly impacts the implementation of the general safety requirement laid down in the framework Regulation[92] and the achievement of its market and safety objectives. In particular, and as witnessed by the majority of stakeholders (across most categories), the lack of specific (implementing) measures for some FCMs hampers the achievement of the two objectives laid down in Article 1 (*purpose and subject matter*) of the framework Regulation: ensuring the effective functioning of the internal market and securing a high level of protection of human health and the interest of consumers.

Why is the lack of EU specific measures for some FCMs hampering the effective functioning of the internal market and compromising FCM safety?

[90] For the FCMs listed in Annex I to Regulation (EC) No 1935/2004.
[91] Listed in Annex I to framework Regulation (EC) No 1935/2004.
[92] In particular, Article 3 thereof.

4.1.1.1. The lack of EU specific measures for some food contact materials: internal market considerations

In the absence of EU specific measures for the articles/materials listed in Annex I to Regulation (EC) No 1935/2004, Member States are allowed to maintain/adopt such measures at national level[93]. These national rules might divert from one Member State to another. For example: a substance might be forbidden in one Member State, authorised under certain limits and conditions in another, or not be regulated at all in a third one. Differences in technical rules imply the application of the principle of *mutual recognition*, according to which any product which is lawfully produced and marketed in one Member State, must, in principle, be allowed for marketing in any other EU Member State. Member States can suspend the marketing of the product for reasons related to safety and health of the users.

In their responses, stakeholders (mainly businesses but also competent authorities) refer to differences in the application of the mutual recognition principle from one Member State to another, which, in their opinion, constitutes a market barrier and destroys the effective functioning of the internal market. Thus, to meet the rules of the national market(s) where the FCMs (substances) is/are intended to be marketed, businesses often need to open parallel process/supply lines. The latter increases their production costs thus creating competitive disadvantages and loss of competitiveness compared to importers from third countries, but also compared to other (mainly harmonised) food contact materials: the next in the supply chain would always prefer the FCM that is cheaper, and with proven safety compliance.

In addition, petitioning for authorisations of substances under different national regimes is reported by businesses as a source of multiplied compliance costs. These costs have direct negative impacts on businesses, such as delayed access to markets, but also on consumers, because opportunities for safety improvement are lost as a result of suspended application of innovation in FCM manufacturing and procession.

Wherever specific measures were not adopted either at EU or at national level, and to ensure compliance with the general safety requirements, businesses often apply the so-called 'self-assessment' (as a form of industry 'self-regulation') or voluntarily comply with, for example, Council of Europe resolutions, third countries' legislation, etc. However, self-regulation and/or voluntary compliance do not constitute a legal basis for enforcement by the national competent authorities and thus could be rejected by Member States. As reported by both businesses and competent authorities, this situation implies additional compliance and enforcement costs.

Increased compliance and enforcement costs have direct negative impacts, not only on businesses and competent authorities, but also on consumers who inevitably pay for the costs at the end of the supply chain.

[93] As already mentioned, the Joint Research Centre of the European Commission conducted a study aimed at identifying existing national FCM measures and challenges pertinent to their implementation. The Commission's evaluation of the final report of the JRC study is ongoing.

4.1.1.2. The lack of EU specific measures for some food contact materials: safety considerations and the protection of human health

In terms of securing FCM safety, the lack of EU specific measures for certain FCMs listed in Annex I to Regulation (EC) No 1935/2004 means that there are no uniform safety standards, e.g. limits for substances, usage conditions, single standards for analytical (testing) methods etc. for the relevant FCM (substances). This leads to a somewhat paradoxical situation where, although they might differ from one Member State to another, all safety standards established at national level are to be considered as equally guaranteeing the safety of the relevant FCM (substance). However, in practice, uniform level of safety cannot be secured, if different standards are to be complied with.

In addition, the absence of EU specific measures may lead to a situation where one and the same FCM is tested with different methods across companies and Member States. Some businesses report that the testing methods are not always suitable to reflect the unique properties of the individual food contact material that they manufacture/process. Not only does this create room for misleading and debatable results as regards the migration behaviour and risk assessment of substances, but it also creates legal uncertainty for both businesses and competent authorities. Debatable results do not necessarily guarantee safety but do increase compliance and enforcement costs.

In addition, one and the same substance might be regulated at EU level for harmonised materials but not regulated at EU level for other non-harmonised materials. As shared by several stakeholders, this is the case of *Bisphenol A*, for example. This substance is regulated at EU level for plastics (harmonised), but is not regulated for coatings (non-harmonised) where this substance is largely used. This means that, in practice, safety of one and the same substance used in different FCM applications cannot be equally secured.

As a result, without uniform safety standards set up at EU level, the general safety legal requirements of the framework regulation are difficult to be complied with and enforced, and FCM safety cannot be uniformly secured. This ultimately results in major and often unknown impacts on human health. The latter is confirmed by several stakeholders across most categories of respondents.

4.1.1.3. Conclusions

The lack of specific measures for some FCMs results in internal market barriers, increased compliance costs, which are eventually covered by end consumers, loss of competitiveness and innovation, and delayed market access for businesses. Market barriers, and in particular, petitioning for authorisations under differing national rules also result in loss of opportunities for food safety improvement via innovation. The lack of uniform EU safety standards for some FCMs (substances) also means that uniform safety across the EU could not be ensured in practice. Thus, without EU specific measures for some FCMs the general EU FCM safety requirements, established in the framework Regulation, could not be fully complied with and enforced.

4.1.2. Stakeholders' key recommendations

The large majority of stakeholders participating in the survey - across businesses, competent authorities, consumers, health/environmental NGOs and researchers -

recommend the adoption of specific measures at EU level for non-harmonised FCMs, so that the effective functioning of the internal market and safety of the relevant FCMs could be ensured.

Several stakeholders (across all categories recommending the adoption of EU specific measures) have expressed their views as regards the *scope* of the recommended specific measures as well as the *approach* to be followed:

4.1.2.1. How to approach harmonisation?

The adoption of specific measures at EU level is referred to as a 'time-consuming' process[94]. According to the Commission, 'In order to prioritise the risk management of food contact materials, decisions to progress and adopt further specific measures are based on available information and evidence about the risk to consumer health as well as the internal market and take account of the principles of subsidiarity and proportionality. This is done in a structured manner in applying the COM Better Regulation principles'[95].

Stakeholders (across all categories recommending the adoption of EU specific measures) demonstrate awareness of the fact that a possible harmonisation exercise for all 13 FCMs currently not covered by EU specific measures would be a time-consuming process. Several stakeholders have come up with recommendations aimed at mitigating time constraints.

In particular, stakeholders tend to **recommend that the adoption of specific measures at EU level should be prioritised.** See Graph 2.
Several stakeholders (mainly across businesses and competent authorities) have made general comments as to the *approach* followed so far for the **harmonisation of plastics**. While some stakeholders recommend the 'plastics' approach as a good example to be followed, others would prefer simpler and more flexible rules allowing for the latest scientific developments to be followed or even alternative regulatory approaches. Some stakeholders' recommend that the adoption of specific measures should be based on, for example, the work done so far by the Council of Europe, the so-called 'ESCO report'[96]. However, no clear trend could be established.

On a more individual basis, stakeholders (mainly consumers, health/environmental NGOs and researchers) also recommend the following *approaches* to regulating currently non-harmonised FCMs:

- policy-making in the field of FCM should be led by the precautionary principle[97] as regards substances;

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[94] See the conclusions of the conference 'Food contact materials: Working together for safety and innovation in Europe' organised by the Luxembourg Presidency of the Council of the European Union on 30 September 2015.
[95] Opinion expressed by the European Commission in response to this stakeholders' survey. See Part 3 of this study.
[96] Report of the ESCO Working group – EFSA's 'Scientific Cooperation Projects' Working Group on non-plastic food contact materials, 2011.
[97] As defined in Article 7 of the EU General Food Law Regulation (EC) No 178/2002. See also Bourguignon D., "The precautionary principle: definitions, applications and governance", In-depth analysis, EPRS, 2015

- SVHS substances (such as CMR, PBT, vPvBs) should not be authorised / should be banned;
- substances banned in FCMs should not be authorised in toys, cosmetics and other sources of chemical exposure and vice versa;
- horizontal rules should be inserted in Regulation (EC) No 1935/2004 for substances not evaluated and authorised at EU level (such as general exclusion of carcinogenic, mutagenic, endocrine disruptor substances in FCM manufacture).

Although EU specific measures are in place for plastics, ceramics and active and intelligent materials, some stakeholders (mainly across businesses and competent authorities) consider that **up-dates are necessary.**

For the majority of stakeholders (across almost all categories) **guidance at EU level is necessary to clarify how legal requirements are to be applied in practice so that uniform compliance with the rules can be ensured**. Some stakeholders (especially among competent authorities) recommend that guidance is legally binding, which would create a legal basis for enforcement of compliance and would avoid misinterpretations.

4.1.2.2. What should fall within the scope of harmonisation?

As a general trend, stakeholders from the above categories **recommend that EU specific measures should set up a single standard for analytical (testing) methods**, such as composition determination, migration testing, risk assessment, but also specific methods for compliance enforcement, thus ensuring that the relevant FCM is tested with one and the same method across the EU (companies and competent authorities). Furthermore, the single EU standard for analytical (testing) methods should be specific for each FCM, thus reflecting its unique properties and avoiding situations where non-harmonised FCMs are tested with methods developed for harmonised FCMs which involve risks of misleading and disputable testing results.

Stakeholders from the different categories recommending further EU-level harmonisation have come up with concrete recommendations as regards: setting up positive lists, limits for substances, testing (including risk assessment) methods to be used etc.

4.1.2.3. Science and FCMs

In their responses, several stakeholders (across most categories) insist that specific measures should be based on scientific evidence. However, as a general trend, stakeholders tend to consider that harmonised FCMs (plastics in particular) are sufficiently studied, or at least more so, than non-harmonised FCMs. Almost all non-harmonised FCMs are mentioned (mainly by competent authorities) as requiring more research. The submitted data does not allow always for a link to be established between knowledge needs and the relevant materials. Therefore, recommendations as regards specific food contact materials cannot to be drawn up for every single material.

Some specific recommendations

Some **recommendations** are worth mentioning, however, as they represent a trend in stakeholders' responses:

- key players in possession of FCM scientific knowledge (such as the EU-Reference Laboratory for FCMs and other relevant services of the European Commission, EFSA, national competent authorities and reference laboratories as well as relevant national research centres[98], individual FCM researchers, standardisation institutions (e.g. CEN, ISO), businesses, consumer, health and environmental organisations, and others) should cooperate to ensure reliable scientific basis for the adoption of specific measures and authorisations of substances; in particular, future cooperation should take into account the experience of cooperation fora such as EFSA's Food Ingredients and Packaging (FIP) Scientific Network, and the Network of national reference laboratories for FCMs; several stakeholders are very specific in recommending that cooperation in terms of FCM research should be coordinated at EU level;
- state-of-the-art scientific knowledge - especially as far as substances' behaviour, and analytical (testing) methods are concerned - on both harmonised and non-harmonised FCMs should be mapped, thus allowing for concrete research needs to be identified for the relevant materials;
- available scientific evidence should be used in a timely manner by (EU) policy-makers thus ensuring that innovation, safety and market access are not compromised;
- substances used as starting materials should be better documented, thus facilitating further research but also traceability and controls;
- several unknowns in research, such as:
    - NIASs present in finished food contact materials and articles which are difficult to be risk assessed,
    - the accumulated (cocktail) effects of substances to which human beings are exposed from different sources, as well as
    - the effects of recycling products used in FCMs manufacture and procession

  should be subject to dedicated research efforts by the key players possessing FCM scientific knowledge, thus allowing for better risk assessment and hence safety improvement;

EFSA's Opinion

At the end of January 2016, EFSA issued an Opinion on '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 (FCM)'. Before adoption, the draft opinion was shared with Member States (FIP Network on FCM) and underwent a public consultation launched in July 2015[99].

[98] Here, 'national' refers to both EU Member States and EEA countries.

[99] A dedicated question (Q 40) was included in the questionnaire addressed to EFSA: 'What criteria do you use to decide if you should open a public consultation in the field of FCM, as for example the one launched in July 2015?'. EFSA replied as follows: 'In line with EFSA policy on transparency – any guidance document on safety assessment is submitted for public consultation – also for highly sensitive subjects (e.g. BPA); results become available at the same time of the publication of the adopted opinion'.

In particular, EFSA's experts recommend 'refining of the safety assessment of substances used in FCM, including the introduction of a more comprehensive approach to estimate consumer exposure, particularly for infants and toddlers. In particular, EFSA's opinion has made the following proposals:

- Identification and evaluation of all substances that migrate should focus more on the finished materials and articles, including the manufacturing process used, rather than concentrating on the substances used.
- For consumer exposure, EFSA's experts propose setting four default food categories driven by infants' and toddlers' food consumption, that are approximately 9, 5, 3 and 1.2 times higher than the current default for consumption (i.e. 17 gr/kg bw per day[100]). Using these default categories would give a higher level of protection for consumers, particularly for infants and toddlers.
- The amount of toxicity data needed should be related to the expected human exposure (three thresholds: 1.5, 30 and 80 µg/kg bw per day[101]). This applies to all migrating substances, i.e. both intentionally and non-intentionally added substances (including oligomers).
- Genotoxicity testing for substances used in FCM should be mandatory even if at low level of exposure. Alternative methods to animal testing could have increased importance for the safety assessment of NIAS.

EFSA's Opinion is now being studied by the European Commission which will discuss with Member States the implications of these refinements for risk management and will advise EFSA on the necessary level of protection for consumers. Depending on the feedback received by the Commission[102], EFSA would prepare the technical guidance for applicants.

In addition, a challenge of concern is the sustainability of EFSA's capacity to provide scientific expertise (opinions on risk assessment) prior to authorisations, especially if EU specific measures are adopted for the 13 FCMs that are not harmonised yet. As indicated by EFSA itself: 'The model of EFSA's scientific Panels and working groups works well. However, **vigilance is required concerning its sustainability in the future as the number of applications, decreasing participation of experts with the requisite expertise, the lack of public laboratories, and the lack of experts in safety assessment may be limiting factors**'[103].

[100] Consumption level in gr/kg bw per day = grams per kilo of body weight per day.
[101] Exposure level in µg//kg bw per day = micrograms per kilo of body weight per day.
[102] At the date of the official publication of this study, the European Commission is considering EFSA's opinion.
[103] Opinion expressed by EFSA in response to this stakeholders' survey.

4.2. Problems inherent to the implementation of existing EU FCM rules. Stakeholders' key recommendations

4.2.1. Traceability of FCMs

4.2.1.1. Traceability problems

Traceability is an important element of the implementation of current EU FCM rules and, thus, directly impacts both the effective functioning of the internal market and safety of FCMs. The relevant requirements are laid down in Article 17 of Regulation (EC) No 1935/2004. In particular, the traceability of FCMs should be ensured at all steps in the supply chain in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility. This requirement is applicable to both harmonised and non-harmonised FCMs.

As already stressed, some categories of stakeholders to which this question was addressed, (especially businesses and competent authorities), perceive DoCs as instruments ensuring traceability. However, under Regulation (EC) No 1935/2004 traceability is limited to identifying the business from which goods have been received and to which they have been provided and does not depend on the availability of DoCs. Nevertheless, the responses from stakeholders among businesses and competent authorities show that they perceive DoCs and the information included therein, on composition and compliance of the goods, as an integral part of traceability. The availability and/or quality of DoCs therefore influences the assessment of achieving traceability throughout the production and distribution chain.

In the absence of EU specific measures for some FCMs, Member States may adopt national provisions for declarations of compliance. The data submitted by stakeholders did not allow for a clear distinction to be made between implementation problems associated with traceability and compliance documentation, on the one hand, and the availability or lack of EU specific measures for concrete FCMs, on the other. Therefore, the problems and recommendations listed below refer generally to traceability and relevant compliance documentation of both harmonised and non-harmonised FCMs.

Stakeholders (mainly businesses and competent authorities) report on problems with traceability and relevant compliance documentation, and declarations of compliance, in particular. There are two **major pertinent problems shared by both businesses and competent authorities:**

- the very availability of compliance documentation (according to stakeholders, there are cases where such documentation is not available at all);
- the quality - accuracy, completeness and hence reliability - of available compliance documents.

Some businesses and competent authorities raise **concerns as regards the lack of requirements for proper identification** (e.g. code marking) **of FCMs** (relevant batches, lots, etc.), so as to allow for indication of FCM business operators and their place in the supply chain, FCMs' origin, etc.

A major issue of concern for both businesses and competent authorities is the availability and quality of compliance documentation accompanying FCMs imported from third

countries. As reported by stakeholders, imported FCMs might be subject to less stricter rules than those established in the EU, which raises concerns in terms of safety and competition.

4.2.1.2. Stakeholders' key recommendations on improving traceability

As a general trend, the following **recommendations** were made by stakeholders (mainly by businesses and competent authorities, both directly involved in ensuring traceability):

- **dedicated training is recommended to FCM business operators** (including to food producers), who are responsible for preparing the compliance documentation, aimed at improving their knowledge as regards relevant legal requirements and improve the information flow along all stages of the supply chain (recommendation made by competent authorities but also from businesses reporting on problems between businesses when exchanging information in the supply chain);
- **dedicated training is recommended to enforcement officers**, so as to ensure uniform controls and enforcement activities across the Member States, especially as far as harmonised FCMs (i.e. those subject to uniform EU safety standards), are concerned (recommendation made by businesses);
- **traceability of imported FCMs and cooperation with third countries should be improved** (recommendation made by both competent authorities and businesses) so as to ensure that the burden of compliance is equally shared by importers placing FCMs on the EU market;
- **the introduction of requirements for proper identification** (e.g. code marking) **of FCM**(s) (i.e. relevant batches, lots, etc.) **should be considered**, so as to facilitate the traceability of FCMs and in particular, the identification of the business operators in the supply chain, the origin of the FCM(s), etc.

The following **recommendations** were also made (mainly by competent authorities) as regards traceability and relevant compliance documentation:

- a requirement for mandatory declarations of compliance for all FCMs to be set up at EU level thus facilitating the process of documenting traceability;
- obligatory registration of business operators;
- the obligation for food producers to inform the competent authorities about non-compliance (under Article 19 of Regulation (EC) No 178/2002) to be extended to FCM business operators dealing with FCMs not yet in contact with food are directly sold to the consumer;
- withdrawals should be better covered by the plastics Regulation (EU) No 10/2011;
- conditions of use should be better reflected in the relevant declarations of compliance.

4.2.2. Controls of food contact materials

4.2.2.1. Problems associated with controls of food contact materials

Verifications of compliance of FCMs fall within the scope of Regulation (EC) No 882/2004 on food and feed official controls aimed at ensuring *uniformity* of controls along the food chain. In particular, Article 1 of the Regulation requires that 'Member States shall ensure that official controls are carried out *regularly*, on a risk basis and with appropriate frequency ...'.
Under this EIA survey businesses and competent authorities were asked to assess the intensity of FCM controls by choosing among the following three options:

1. no official controls are carried out,
2. official controls are carried out from time to time on a routine basis,
3. extensive and *regular* official controls are carried out.

The majority of businesses and half of competent authorities share a common perception that controls are carried out 'from time to time on a routine basis' while Regulation 882/2004 would seek that controls are carried out 'regularly'.

Furthermore, the majority of businesses, participating in the survey, report that differences in the intensity of controls for one and the same FCM do exist across the EU. Some businesses are very specific to report that in some Member States the relevant FCM are not controlled at all without giving concrete examples.

Although this observation is based on perceptions only, they point to differences as regards the intensity of controls by competent authorities. If this is really the case in practice, it would mean that controls are not carried out in a *uniform* way across the EU, as required by Regulation (EC) No 882/2004 on food and feed official control.

4.2.2.2. Stakeholders' key recommendations on improving controls of food contact materials

The data submitted under this survey is not enough for the above assumption to be proved or ruled out. Therefore, further research on the **intensity of control activities is justified[104].** This future study should also include in its scope the very control activities and compliance documentation problems, which, for stakeholders (mainly businesses and competent authorities) are associated with challenges. Controls on imports from third countries should also be addressed by this future research work. Thus the results of a possible study spotting control experiences would constitute a valuable basis for development of further legal (harmonisation) provisions but also non-legal instruments (Guidance documents) at EU level.

Furthermore, on a more individual basis, the following **recommendations** were made (mainly by competent authorities) as regards controls:

- a special working group for FCM control authorities (similar to PEMSAC at the cosmetic area) should be established to discuss the practical aspects of FCM official controls;
- the Commission should plan and launch joint control campaigns such as, for example, the joint Nordic campaign on declarations of compliance, so that better

[104] This is not a strict recommendation by stakeholders, but by the author(s) of this European Implementation Assessment study.

and more uniform implementation of FCM rules among all the Member States; in particular, the EU-wide FCM controls campaign on lid gaskets is assessed as positive by some competent authorities and recommended as a model to be followed in the future (also possibly with EU funding).

4.3. Final implementation assessment

4.3.1. Assessment against the set of 'key assessment criteria' for evaluations: relevance, coherence, European added value, effectiveness and efficiency

The following conclusions are solely based on the responses submitted by stakeholders (mainly across the categories of businesses, competent authorities, consumers, health/environmental organisations and researchers).

Relevance
For stakeholders (across all categories) the original EU FCM policy objectives (as laid down in Article 1 of Regulation (EC) No 1935/2004) are relevant to real needs. Stakeholders do not consider the incorporation of new objectives necessary. Thus, for all categories of stakeholders participating in the survey, EU intervention in the field of FCMs is still relevant and necessary.

Coherence
For the large majority of stakeholders, the lack of EU specific measures for some FCMs makes the current EU FCM legal framework incomplete and incoherent to the extent that the requirements laid down in Article 3 of Regulation (EC) No 1935/2004 are difficult to be complied with by relevant business and enforced by competent authorities. No other comparable interventions could be assessed.

EU added value
For the large majority of stakeholders, the EU FCM policy could not be replaced by interventions at Member States' level. On the contrary, the value that the intervention at EU level has added to the effective functioning of the internal market and FCM safety is acknowledged by stakeholders. However, this is only true for FCMs that are currently covered by specific measures at EU level. Hence, the adoption of specific measures at EU level for those FCMs that are not yet harmonised is recommended by stakeholders.

Effectiveness
Generally, for stakeholders, the achievement of the original objectives is conditional upon the availability of specific measures at EU level for the relevant FCM. Wherever such measures have not been adopted, both the functioning of the internal market and FCM safety are negatively affected.

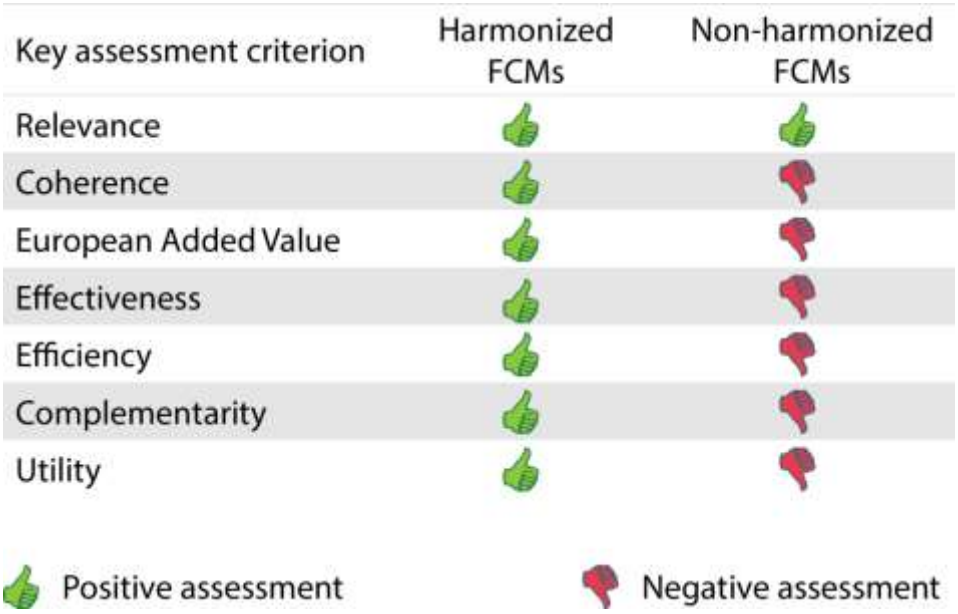
Efficiency
Where the lack of specific measures at EU level has resulted in national rules, efficiency is compromised by the need for businesses to comply with multiple source legislation which leads to multiplication of costs transferred downwards to the end of the supply chain and consumers. Thus, the costs (including monetary, staff costs, etc.) spent by businesses to ensure compliance, and by competent authorities to enforce compliance for non-harmonised FCMs, are unjustifiably higher than for harmonised FCMs.

4.3.2. Assessment against additional assessment criteria: utility and complementarity

Complementarity
EU FCM policy is confirmed by a tiny majority of stakeholders (mainly across businesses and competent authorities) as supporting and usefully supplementing related EU policies, while for consumer and health/environmental NGOs it is not confirmed. It might be the case, however, that other related policies do not support or usefully supplement the EU FCM policy.

Utility
The utility of the intervention is confirmed as regards harmonised FCMs (mostly across businesses and competent authorities) and questioned as regards non-harmonised FCMs (across most categories).

Figure 2: Stakeholders' final implementation assessment



5. Conclusions

This in-house European Implementation Assessment study presents the results of a stakeholders' survey conducted by the Ex-Post Impact Assessment Unit of the European Parliamentary Research Service (EPRS) between December 2015 and February 2016. It seeks to assess the implementation of existing EU FCM rules, and, in particular, framework Regulation (EC) No 1935/2004, which is the focus of a dedicated Implementation Report being prepared by the EP Committee on Environment, Public Health and Food Safety and for which it aims to provide background support.

Based on stakeholders' responses, problems inherent to both the EU FCM legislation itself and to its implementation were identified.

For a large majority of stakeholders (across almost all categories), **the current legal framework** regulating food contact materials at EU level is not complete. The lack of specific measures for most food contact materials[105] directly impacts the implementation of the general safety requirements laid down in Regulation (EC) No 1935/2004[106] and the achievement of its objectives. In particular, as reported by stakeholders, for non-harmonised materials effective functioning of the internal market and consumer safety could not be fully ensured.

The lack of specific measures for some food contact materials results in internal market barriers, increased compliance costs (which are eventually covered by end consumers), loss of competitiveness and innovation, and delayed market access for businesses.

Market barriers, and in particular, petitioning for authorisations under differing national rules also results in loss of opportunities for food safety improvement via innovation. The lack of uniform EU safety standards for non-harmonised FCMs (substances) also means that uniform safety across the EU cannot be ensured in practice. Thus, without EU specific measures for some FCMs the general EU FCM safety requirement established in framework Regulation (EC) No 1935/2004[107], cannot be fully complied with and enforced.

Therefore, stakeholders recommend the adoption of specific measures for the articles and materials not yet harmonised at EU level. Generally, stakeholders are aware that full harmonisation of all currently non-harmonised FCMs is a time-consuming process. Therefore, they recommend the adoption of specific measures for some materials which they consider to be a matter of priority. Thus paper & board is candidate 'number one' for adoption of specific measures at EU level[108], as recommended by the majority of stakeholders participating in the survey.

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[105] Listed in Annex I to Regulation (EC) No 1935/2004, and for which specific measures at EU level could be adopted.

[106] According to Article 3 of Regulation (EC) No 1935/2004 food contact materials and articles should be 'manufactured in compliance with **good manufacturing practice**, so that, under normal and foreseeable conditions of use, they do not transfer their constituents to food in quantities that could endanger human health, bring about an unacceptable change in the composition of the food, or a deterioration of its organoleptic characteristics'.

[107] See previous footnote.

[108] Under Article 5(1) of framework Regulation (EC) No 1935/2004.

As a general trend, the stakeholders that are in favour of further EU level harmonisation, recommend that EU specific measures should set up a single standard for analytical (testing) methods, such as composition determination, migration testing, risk assessment, but also specific methods for compliance enforcement, thus ensuring that the relevant FCM is tested by companies and competent authorities across the EU with one and the same method. Furthermore, the EU single standard for analytical (testing) methods should be specific for each FCM, thus reflecting its unique properties and avoiding situations where non-harmonised FCMs are tested with methods developed for harmonised FCMs which involve risks of misleading and disputable testing results.

In their responses several stakeholders (across most categories) insist that the adoption of specific measures at EU level should be based on scientific evidence. However, as a general rule, FCMs are often associated with research challenges. Thus, stakeholders have come up with recommendations aimed at overcoming issues of major concern such as, for example, proper identification of both starting substances (i.e. those used at the beginning of FCM manufacturing/procession), but also the so-called 'non-intentionally added substances' (created as a result of chemical reactions and the presence of which in finished food contact materials and articles remains unknown), etc. In particular, cooperation between the key players possessing FCM scientific knowledge, aiming at overcoming the identified research challenges, is a common recommendation.

For stakeholders, **the implementation of existing EU FCM rules** is also associated with problems. In particular, day-to-day implementation problems refer to traceability and official controls.

In terms of traceability, implementation problems reported by stakeholders (mainly across businesses and competent authorities) are related mostly to the availability and quality (accuracy, completeness and hence reliability) of compliance documentation (also for imported FCM products) which, according to stakeholders, hinders proper traceability. Thus, among others, both businesses and competent authorities recommended dedicated training aimed at improving each other's compliance and enforcement capacities, and improvement of traceability of imported FCM products.

As far as official controls are concerned, stakeholders' responses suggested that control activities are not carried out with the same intensity across Member States. In particular, the majority of businesses and half of competent authorities share a common perception that controls are carried out 'from time to time on a routine basis' while Regulation 882/2004 on food and feed controls would seek that controls are carried out 'regularly'. Furthermore, the majority of businesses participating in the survey report that differences in the intensity of controls for one and the same FCM do exist across the EU. Although this observation is based on perceptions only, it points to differences as regards the intensity of controls across the Member States for one and the same material. The data submitted under this survey is not enough for the latter assumption to be proved or ruled out. Therefore, further research on the intensity of control activities, as well as pertinent traceability issues of concern, is justified. The results of a possible study identifying control experiences would constitute a valuable basis for the development of further legal (harmonisation) provisions as well as non-legal instruments (guidance documents) at EU level.

Finally, **an assessment of the state of implementation made on the basis of the set of key assessment criteria** for evaluations showed that the current EU FCM policy

objectives were assessed as relevant to stakeholders' needs. The added value of FCM rules established at EU level was welcomed - for a large majority of stakeholders, there is no alternative to EU-level harmonisation of food contact materials. However, while effectiveness, efficiency and coherence were confirmed for FCMs harmonised at EU level, the fulfilment of these criteria as regards non-harmonised FCMs was questioned by stakeholders. This would suggest that further action at EU level, in terms of both legislative and non-legislative measures, might be necessary in order to meet the remaining implementation challenges.

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Other sources

Conclusions of the conference 'Food contact materials: Working together for safety and innovation in Europe' organised by the Luxembourg Presidency of the Council of the European Union on 30 September 2015

McCombie, G., Grob, K., Biedermann, M., Harling, A, and Altkofer, W. Migration of plasticizers from lid gaskets: European campaigns (infographic), Kantonales Labor Zürich and Chemisches- und Veterinäruntersuchungsamt-Stuttgard, (year of publication is not available)

Annex I

3.1 Assessment of current EU FCM rules

3.1.1 Assessment of the current EU FCM policy objectives and instruments (checking Relevance and Coherence)

№	Question	Business – manu-facturers and/or processors	Business - dis-tributors	Business – directly using FCM products	MS[109]	COM[110]	EFSA[111]	Con-sumers[112]	health / envi[113]	Research-ers
1	*From your perspective, do the original objectives, laid down in framework Regulation 1935/2004, still correspond to real needs? Please reply by 'yes' or 'no'. If you have replied by 'no', please briefly describe what the objectives should be from your perspective?*	√	√	√	√	√	√	√	√	√
2	*From your perspective, are current EU FCM rules still relevant to the original objectives? Please reply by 'yes' or 'no'. If you have replied by 'no', please briefly describe why?*	√	√	√	√	√	√	√	√	√
3	*From your perspective, are there other possible policy*	√	√	√	√	√	√	√	√	

[109] Member States (competent authorities)
[110] The European Commission's relevant services (DG SANTE and its Directorate Health and Food Audit and Analysis (FVO), as well as the EU Reference Laboratory on Food Contact Materials (EU-RL FCM)) were addressed with a joint questionnaire.
[111] European Food Safety Authority
[112] consumers' organisations
[113] health/environmental organisations

	instruments/measures at EU level (besides legal regulation) that would also support the achievement of the original objectives or of the objectives you have suggested above? Please reply by 'yes' or 'no'. If you have replied by 'yes', please briefly describe the instrument/s and its/their relevance to the original and newly suggested objectives?									

3.1.2 Assessment of the scientific basis on which EU FCM rules are being adopted (checking Effectiveness/Utility)

№	Question	Business – manu-facturers and/or processors	Business - dis-tributors	Business – directly using FCM products	MS	COM	EFSA	Con-sumers	health / envi	Research-ers
4	*From your perspective, which are the articles and materials, and hence substances, that are studied sufficiently, and which are the articles and materials (hence substances) for which scientific knowledge (including analytical methods) still needs to be developed, so as to ensure that the adoption of 'specific measures' at EU and/or national level (including 'authorisations of*	√			√	√	√		√	√

	substances') is based on 'adequate and sufficient' evidence?									
5	*In your opinion, are new developments in research sufficiently taken into account by EU and national policy-makers when setting up new FCM rules at EU and national level (including 'specific measures' for the articles and materials listed in Annex I to Regulation (EC) 1935/2004 and 'authorisations' of substances)? Please, reply by 'yes' or 'no'. If you have replied by 'no', please briefly describe why.*	√	√	√	√	√	√	√	√	√
6	*Please briefly describe the most important challenges related to studying food contact articles/materials and relevant substances.*					√	√		√	√
7	*How would you assess your capacity when it comes to accomplishing your tasks under Article 24 (3) of Regulation (EC) No 1935/2004? Please, choose between: 'sufficient' or 'insufficient'. In both cases, please briefly explain why.*					√				
8	*How would you assess your scientific capacity when it comes to providing independent, reliable*						√			

	and up-to-date scientific knowledge? Please, choose between: 'sufficient' or 'insufficient'. In both cases, please briefly explain why.									

3.1.3 Mapping and assessing the state-of-play as regards EU specific measures under Article 5 (1) o Regulation (EC) No 1935/2004
(checking Relevance/Effectiveness/Utility)

№	Question	Business – manu-facturers and/or processors	Business - dis-tributors	Business – directly using FCM products	MS	COM	EFSA	Con-sumers	health / envi	Research-ers
9	*On what grounds does the Commission decide for which of the materials and articles (listed in Annex I) to prepare draft 'specific measures' under Article 5 of framework Regulation (EC) No 1935/2004? Please explain briefly.*					√				
10	*How many cases were there in which the Commission has decided to propose the authorisation of a substance against the negative opinion of EFSA and vice versa - positive opinion of EFSA but the Commission refuses to authorise? Please briefly explain the grounds.*					√				

11	***In preparing your Member State's position for the Regulatory Procedure with Scrutiny, do you involve the relevant stakeholders - e.g. consumers, businesses? Is your cooperation with the relevant stakeholders based on legal requirements or not? If you have replied by 'yes', please provide a link to the legally binding rules.***				√					
12	***In the absence of 'specific measures' at EU level, has your Member State adopted provisions at national level, including lists of 'authorised' substances? If your Member State has adopted such provisions, please specify for which articles/materials.***				√					
13	***In your FCM sector, what rules do you comply with in the absence of 'specific measures' at EU level for the respective article/material? What are the main challenges related to such compliance? Please disregard this question, if irrelevant.***	√								

14	*In your sector, is there national legislation (inside or outside the EU) laying down lists of 'authorised' substances that you should comply with? If you have replied by 'yes', please, specify the country.*	√								
15	*Do you think that the absence of 'specific measures' at EU level for some articles and materials negatively affects the internal market and safety of FCMs? Please, reply by 'yes' or 'no'. If you have replied by 'yes', please briefly explain why. Please disregard this question, if it is irrelevant to the article/material your members are working on.*	√	√	√				√	√	
16	*From your perspective, what articles and materials should be further regulated and at what (EU or national) level? Please explain the reasons both in terms of FCM safety and functioning of the internal market.*	√	√	√	√	√	√	√	√	√

3.1.4 Mapping and assessing current rules on 'good manufacturing practice' and related documents (declarations of compliance) (checking Effectiveness)

№	Question	Business – manu-facturers and/or processors	Business - dis-tributors	Business – directly using FCM products	MS	COM	EFSA	Con-sumers	health / envi	Research-ers
17	*Has your sector established specific 'good manufacturing practice (GMP)' guidelines for the relevant article/material? If you have replied by 'yes', please indicate a link to these guidelines. Please disregard this question, if irrelevant.*	√								
18	*From your perspective, are the current EU and sector-specific GMP rules sufficient to ensure safety of the articles and materials? Please reply by 'yes' or 'no'. If you have replied by 'no', please, briefly describe why the current EU and sector-specific GMP rules for the particular article/material are insufficient.*	√	√							
19	*In the absence of EU 'specific measures' for the FCMs that your sector is working on, are there any other requirements for 'Declarations of Compliance' (DoCs) and relevant 'appropriate documentation' that*	√								

	your members are supposed to comply with? Please specify the authority/authorities laying down these requirements. Please disregard this question, if irrelevant.									
20	*In the absence of EU 'specific measures' for the articles and materials listed in Annex I to Regulation (EC) No 1935/2004, has your Member State adopted provisions laying down a requirement for 'Declarations of Compliance' and relevant 'appropriate documentation' to be made available by businesses? Please, specify the authority laying down these requirements.*				√					

3.2 Assessment of the implementation of current EU FCM rules

3.2.1 Assessment of the implementation of good manufacturing practices and related documents (declarati of compliance)
(checking Effectiveness/Efficiency)

№	Question	Business – manu-facturers and/or processors	Business - dis-tributors	Business – directly using FCM products	MS	COM	EFSA	Con-sumers	health / envi	Research-ers
21	*From your perspective, please describe the main challenges (e.g. costs for risk assessments) related to the implementation of the current EU and*	√	√							

	sector-specific GMP rules, and relate them to the different types of enterprises: large-, medium-, small- and micro-sized ones.									
22	***From your perspective, is the very availability of a 'Declaration of compliance' and 'appropriate documentation' ensuring that the particular article/material (covered or not by EU 'specific measures') complies with the rules applicable to this article/material? Please reply by 'yes' or 'no'. If you have replied by 'no', please briefly describe why.***	√	√	√	√					
23	***From your perspective, are the current EU FCM rules sufficient to ensure traceability in the supply chain? Please reply by 'yes' or 'no'. If you have replied by 'no', please briefly describe why. Please also comment on the main challenges related to the implementation of traceability rules and relate them to the different types of enterprises: large-, medium-, small- and micro-sized ones[114].***	√	√	√	√	√	√	√	√	

[114] This question slightly varies for each category of stakeholders: businesses and Member States.

3.2.2 Assessment of compliance and enforcement costs generated by the implementation of relevant FCM rules (checking Efficiency)

№	Question	Business – manu-facturers and/or processors	Business - dis-tributors	Business – directly using FCM products	MS	COM	EFSA	Con-sumers	health / envi	Research-ers
24	*From your perspective, how would you assess the 'compliance costs' generated by the current EU FCM rules and national FCM rules (please, also take into account the costs related to the preparation of applications for 'authorisation' of substances at EU or national level)? For each set of rules (EU and national), please assess the costs as 'very high' or 'high' or 'reasonable':* *- EU FCM rules,* *- national (EU Member States),* *- national (third countries).* *If you have replied by 'very high' or 'high', please briefly describe the most burdensome costs and their sources.*	√	√	√						

25	***If possible, please also express the 'compliance costs', generated by EU and national FCM rules (including the costs for authorisation of substances at EU and national level), as a percentage of your relevant members' annual turnover. Please specify what percentage of the 'compliance costs' (declared above) is generated by:*** ***- EU FCM rules,*** ***- national rules (EU Member States),*** ***- national rules (third countries).*** ***Please also briefly describe the different effects of 'compliance costs' on large-, medium-, small- and micro-sized enterprises.***	√		√						
26	***From your perspective, how would you assess the 'enforcement costs' generated by current EU FCM rules? Please select between 'very high', 'high' or 'reasonable'. If you have replied by 'very high' or 'high', please briefly describe the most burdensome costs and their sources. If possible, please also express 'enforcement costs' in budgetary***				√					

	terms.									

3.2.3 Assessment of compliance and enforcement (control) activities and cooperation between relevant stakeholders (checking Effectiveness/Efficiency/Utility)

№	Question	Business – manu-facturers and/or processors	Business - dis-tributors	Business – directly using FCM products	MS	COM	EFSA	Con-sumers	health / envi	Research-ers
27	*To which of the following statements, regarding the intensity of controls by competent national authorities, would your sector/competent authority subscribe:* *1. no official controls are carried out,* *2. official controls are carried out from time to time on a routine basis,* *3. extensive and regular official controls are carried out?* *(For businesses only): Are your members witnessing differences in terms of intensity of controls from one Member State to another? Please, reply by 'yes' or 'no'.*	√	√		√					
28	*How would you assess your cooperation with Member States' competent authorities (alternatively businesses) when it*	√	√		√	√				

	comes to controls of compliance with the EU FCM rules? Please choose between 'most often good' or 'most often problematic'. If you have replied with 'most often problematic', please briefly describe the main cooperation challenges.									
29	***In your opinion, are the sanctions (under Article 25 of Regulation (EC) No 1935/2004) laid down by Member States effective, proportionate and dissuasive enough to make businesses respect EU FCM rules? Please explain briefly.***					√				
Consumers and food contact materials. Assessment of cooperation between consumers and relevant stakeholders (checking Effectiveness/Utility)										
30	***When it comes to food contact materials, do your members cooperate with Member States' competent FCM authorities and on what occasions? How would you assess you cooperation with Member States' competent authorities? Please choose between 'most often good' and 'most often problematic'. If you have replied with 'most often problematic', please briefly describe the***			√				√		

	main cooperation challenges. Please, indicate, if your answer would vary from one MS to another.									
31	***Do you enter in contact with consumers and on what occasions? Please describe briefly.***				√					
32	***How would you assess your cooperation with consumers? Please choose between 'most often good' or 'most often problematic'. If you have replied with 'most often problematic', please briefly describe the main cooperation challenges.***				√					
33	***Based on your members' contacts with costumers/consumers, please briefly describe the perception of customers/consumers as regards safety: do they trust FCM safety? Please reply by 'yes' or 'no'. Please also indicate which are the articles and materials (respectively the products manufactured using FCMs, e.g. packaging, kitchenware and***		√	√				√		

	utensils, etc.) that costumers/consumers trust and/or mistrust.									
34	*Do consumers recognise FCM indications on labels such as e.g. the symbol in Annex II to Regulation (EC) No 1935/2004? Please choose between 'most often "yes"' or 'most often "no"'.*		√	√				√		

3.2.4 General implementation assessment

3.2.4.1 Assessment of the achievement of the objectives of the EU FCM policy. Key implementation challenges (checking Effectiveness)

№	Question	Business – manu-facturers and/or processors	Business - dis-tributors	Business – directly using FCM products	MS	COM	EFSA	Con-sumers	health / envi	Research-ers
35	*From your perspective, is the implementation of current EU FCM rules ensuring:* *- the safety of FCM, and* *- the effective functioning of the internal market?* *Please briefly describe the main implementation challenges.*	√	√	√	√	√	√	√	√	

3.2.4.2 Identification and assessment of key economic, social, health and environmental impacts (checking Effectiveness/Utility)

№	Question	Business – manu-facturers and/or processors	Business - dis-tributors	Business – directly using FCM products	MS	COM	EFSA	Con-sumers	health / envi	Research-ers
36	*For each of the following, please, specify (from your perspective) the most important impacts stemming from the implementation of the EU FCM rules and assess them as positive or negative:* *- economic impacts - ... (+/-);* *- social impacts - ... (+/-),* *- environmental/health impacts - ... (+/-).*	√	√	√	√	√	√	√	√	

3.2.4.3 The EU FCM policy and other EU policies (coherence/complementarity)

№	Question	Business – manu-facturers and/or processors	Business - dis-tributors	Business – directly using FCM products	MS	COM	EFSA	Con-sumers	health / envi	Research-ers
37	*From your perspective, do the EU FCM rules support and usefully supplement related EU policies: for example, are the EU FCM rules supporting or preventing the reduction of food waste, proper management of waste, positively or negatively affecting consumer policies or health policies, etc.*	√	√	√	√	√	√	√	√	√

	(if relevant, please, identify and comment on other policy examples)[115]*? Please reply by 'yes' or 'no'. If you have replied by 'no', please briefly describe why.*									

3.2.4.4 Assessment of the added value of the EU FCM policy (checking the 'European added value' criterion)

№	Question	Business – manu-facturers and/or processors	Business - dis-tributors	Business – directly using FCM products	MS	COM	EFSA	Con-sumers	health / envi	Research-ers
38	*Could the results from the implementation of EU FCM rules that you have identified above, be equally or better achieved at Member State level? Please, reply by 'yes' or 'no', and, in both cases, explain why.*	√	√	√	√	√	√	√	√	

Complementary questions

№	Question	Business – manu-facturers and/or processors	Business - dis-tributors	Business – directly using FCM products	MS	COM	EFSA	Con-sumers	health / envi	Research-ers
39	*If you consider it important, please comment on issues which couldn't be raised answering the above questions and also express your recommendations for improvement of current EU FCM rules and their*	√	√	√	√	√	√	√	√	√

[115] It should be noted that the examples given under this question were tailor-made according to the category of stakeholder that it was asked to.

	implementation.									
40	***What criteria do you use to decide if you should open a public consultation in the field of FCM, as for example the one launched in July 2015?***						√			

Annex II

	Name of the stakeholder	Category of stakeholder	FCM	Representativeness/ Membership	Questionnaire forwarded to	Speaks for
1	**Association of the European Adhesive & Sealant Industry (FEICA)**	business (manufacturers and/or processors)	adhesives	webpage		FEICA
2	**The European Ceramic Industry Association (Cerame-Unie)**	Business (manufacturers and/or processors)	ceramics	webpage	European Federation of Industries of Porcelain and Table Earthenware and Ornamentation (FEPF)	FEPF
3	**Confédération Européenne du Liège (C.L.iège)**	business (manufacturers and/or processors)	cork	webpage		C.L.iège
4	**European Tyre & Rubber Manufacturers' Association (ETRMA)**	business (manufacturers and/or processors)	rubbers	webpage		ETRMA
5	**Glass Alliance Europe (GAE)**	business (manufacturers and/or processors)	glass	webpage		GAE
6	**European Container Glass Federation (FEVE)**	business (manufacturers and/or processors)	glass	webpage		FEVE
7	**European Domestic Glass Association (EDG-ESGA) (spontaneous)**	business (manufacturers and/or processors)	glass	webpage		EDG-ESGA
8	**The European Steel Association (EUROFER)**	businesses (manufacturers and/or processors)	metals & alloys	webpage		EUROFER
9	**Association of European Producers of Steel for Packaging (APEAL) (spontaneous)**	business (manufacturers and/or processors)	metals & alloys	webpage		APEAL
10	**Confederation of European Paper Industries (CEPI)**	Business (manufacturers and/or processors)	paper & board	webpage		CEPI
11	**International Confederation of Paper and Board Converters (CITPA)**	business (manufacturers and/or processors)	paper & board	webpage	European Multiwall Paper Sack Industry (EUROSAC)	CITPA

	Name of the stakeholder	Category of stakeholder	FCM	Representativeness/ Membership	Questionnaire forwarded to	Speaks for
12	International Confederation of Paper and Board Converters (CITPA)	business (manufacturers and/or processors)	paper & board		European Corrugated Packaging Association (FEFCO)	CITPA
13	International Confederation of Paper and Board Converters (CITPA)	business (manufacturers and/or processors)	paper & board		European Carton Makers Association (ECMA)	CITPA
14	Association of Plastics Manufacturers (Plastics Europe)	business (manufacturers and/or processors)	plastics	webpage		Plastics Europe
15	European Printing Ink Association (EuPIA, a sector of CEPE)	business (manufacturers and/or processors)	printing inks	webpage		EuPIA
16	European Chemical Industry Council (CEFIC - CES sector)	business (manufacturers and/or processors)	silicones	webpage		CEFIC - CES
17	European Council of Paint, Printing Ink and Artists' Colours Industry (CEPE)	business (manufacturers and/or processors)	(can)coatings	webpage		CEPE
18	European Wax Federation (EWF)	business (manufacturers and/or processors)	waxes	webpage		EWF
19	European Confederation of Woodworking Industries (CEI-Bois)	business (manufacturers and/or processors)	wood	webpage	European Federation of the Wooden Pallet and Packaging Industry (FEFPEB)	FEFPEB
20	European Chemical Industry Council (CEFIC - FCA sector) (spontaneous)	business (manufacturers and/or processors)	additives	webpage		CEFIC - FCA
21	EuroCommerce	business (distributors)	all FCMs	webpage		EuroCommerce
22	FoodDrinkEurope	Business (directly using FCM products)	all FCMs	webpage		FoodDrinkEurope
23	European Commission	(DG SANTE /including FVO/ and EU-RL on FCMs)	all FCMs			
24	European Food Safety Authority	EFSA	all FCMs			
25	Austria	Member State (competent	all FCMs			

	Name of the stakeholder	Category of stakeholder	FCM	Representativeness/ Membership	Questionnaire forwarded to	Speaks for
		authority)				
26	Belgium	Member State (competent authority)	all FCMs			
27	Bulgaria	Member State (competent authority)	all FCMs			
28	Croatia	Member State (competent authority)	all FCMs			
29	Czech Republic	Member State (competent authority)	all FCMs			
30	Cyprus	Member State (competent authority)	all FCMs			
31	Denmark	Member State (competent authority)	all FCMs			
32	Estonia	Member State (competent authority)	all FCMs			
33	Finland	Member State (competent authority)	all FCMs			
34	France	Member State (competent authority)	all FCMs			
35	Germany	Member State (competent authority)	all FCMs			
36	Greece	Member State (competent authority)	all FCMs			
37	Hungary	Member State (competent authority)	all FCMs			
38	Ireland	Member State (competent authority)	all FCMs			
39	Italy	Member State (competent authority)	all FCMs			
40	Latvia	Member State (competent authority)	all FCMs			
41	Lithuania	Member State (competent authority)	all FCMs			

	Name of the stakeholder	Category of stakeholder	FCM	Representativeness/ Membership	Questionnaire forwarded to	Speaks for
42	Luxembourg	Member State (competent authority)	all FCMs			
43	Malta	Member State (competent authority)	all FCMs			
44	The Netherlands	Member State (competent authority)	all FCMs			
45	Poland	Member State (competent authority)	all FCMs			
46	Portugal	Member State (competent authority)	all FCMs			
47	Romania	Member State (competent authority)	all FCMs			
48	Slovakia	Member State (competent authority)	all FCMs			
49	Slovenia	Member State (competent authority)	all FCMs			
50	Spain	Member State (competent authority)	all FCMs			
51	Sweden	Member State (competent authority)	all FCMs			
52	United Kingdom	Member State (competent authority)	all FCMs			
53	European Consumer Organization (BEUC)	Consumers' organisation	all FCMs	webpage	Danish Consumer Council (DCC)	DCC
54	European Consumer Voice in Standardization (ANEC)	Consumers' organisation	all FCMs	webpage		ANEC
55	ChemTrust	Health/environmental organisation	all FCMs	webpage		ChemTrust
56	Food Packaging Forum (FPF)	researchers	all FCMs	webpage		FPF
57	Individual researcher					
58	Individual researcher					
59	Individual researcher					
60	Individual researcher					
61	Individual researcher					

Food contact materials (FCMs) are widely used in everyday life in the form of food packaging, kitchen utensils, tableware, etc. When put in contact with food, the different materials may behave differently and transfer their constituents into the food. Thus, if ingested in large quantities, FCM chemicals might endanger human health, or change the food itself. Therefore, food contact materials are subject to legally binding rules at EU level, currently laid down in Regulation (EC) 1935/2004 which aims to ensure, not only FCM safety, but also the effective functioning of the internal market of FCM goods.

The regulation establishes a general safety requirement applicable to all possible food contact materials and articles, and provides the possibility for adoption of specific safety requirements (i.e. further harmonisation at EU level) for seventeen individual materials/articles. So far, specific safety requirements have been adopted only for four FCMs: plastics (including recycled plastics), ceramics, regenerated cellulose and so-called active and intelligent materials. Where specific requirements have not been adopted at EU level, Member States may adopt such measures at national level. This is the case for several widely used FCMs, such as paper & board, metals & alloys, glass, coatings, silicones, rubbers, printing inks etc.

However, as reported by the majority of stakeholders participating in the survey, the lack of specific measures at EU level for some food contact materials/articles negatively impacts the functioning of the internal market for the material/article concerned and for its food safety. Stakeholders - representing businesses, consumers, environmental and health NGOs, researchers, and Member States' competent authorities - are in favour of specific measures at EU level.

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