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DG Health and Food Safety

OVERVIEW REPORT

Official controls over food contact materials in EU Member States

Health and Food Safety

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OVERVIEW REPORT
OF A SERIES OF FACT-FINDING MISSIONS AND AUDITS
CARRIED OUT IN 2017 AND 2018
CONCERNING OFFICIAL CONTROLS RELATED TO FOOD CONTACT MATERIALS IN EU MEMBER STATES

Executive Summary

The objective of this report is to present an overview on how European Union Member States have integrated controls on food contact materials into their official control systems as foreseen in Regulation (EC) No 1935/2004. This overview is based on information obtained in a series of fact-finding missions and audits in Member States carried out by the Commission services in 2017 and 2018 and discussions held in the framework of two Better Training for Safer Food workshops on strengthening Member States' response to Union audits, which took place in 2017 and 2019.

The series established that in general, competent authorities and official control laboratories in charge of food contact materials are designated in the Member States visited, and to a certain extent, competent authorities can identify the business operators involved in the food contact materials chain by way of a system for registration. The approaches taken to the organisation and implementation of official controls on food contact materials varied in the Member States visited.

In terms of effectiveness, official controls on food contact materials are challenging due to the very technical nature of the subject and the limited availability of suitable analytical methods, allied with difficulties in ensuring that control staff possess the necessary level of technical knowledge and expertise. Risks to human health associated with food contact materials are perceived as relatively low by competent authorities. Controls in this area are not prioritised and, when undertaken, are rather superficial in nature, often mainly focusing on verifying the presence of generic declarations of compliance rather than an in-depth assessment of the evidence supporting such declarations.

This, in combination with an absence of systems for hands-on training for control staff, leads to inspectors not being able to build up the requisite technical knowledge, and therefore not being in a position to evaluate specific and relevant details of declarations of compliance and supporting documentation, as required by the legislation.

The audits found that inspectors could not reliably verify compliance with the general requirements of Regulation (EC) No 1935/2004 and/or with provisions set out under other European legislation covering the safety of food contact materials.

The training courses organised by the Commission services facilitated discussions on the issue with Member States and the identification of common challenges but also potential approaches to official controls which, if adopted, should result in improvements in their overall effectiveness.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
BTSF	Better Training for Safer Food
DG Health and Food Safety	Directorate-General for Health and Food Safety of the European Commission
DoC	Declaration of Compliance
EFSA	European Food Safety Authority
EU	European Union
FBO(s)	Food Business Operator(s)
FCM	Food Contact Material
GMP	Good manufacturing Practices
HACCP	Hazard Analysis and Critical Control Points
NIAS	Not Intentionally Added Substances
NRL	National Reference Laboratory
OCR	"Official Controls Regulation" Regulation (EU) 2017/625
RASFF	Rapid Alert System for Food and Feed

1. INTRODUCTION

This report aims to present an overview on how European Union (EU) Member States visited have integrated controls on food contact materials (FCM) into their official control systems, the challenges faced, the good practices identified and the measures needed to improve these official controls.

It is based on the information obtained by the European Commission's Directorate-General for Health and Food Safety during seven fact-finding missions and audits in 2017 – 2018 (see **Table 1**) and two relevant "Better Training for Safer Food" (BTSF) workshops in 2017 and 2019[(1)].

This work was undertaken within the framework of a Commission evaluation of the EU legislation governing FCM as regards its effectiveness, efficiency, relevance, coherence and EU-added value[(2)].

Food Contact Materials

FCMs are all materials and articles which are intended to come into contact with food including those which are already in contact with food and those which can reasonably be expected to come into contact with food or transfer their constituents into food under normal or foreseeable conditions of use. FCMs include many different types of articles including food packaging, kitchenware and tableware and items used in professional food manufacturing, preparation, storage and distribution. They incorporate a wide range of materials such as glass, metal, paper, plastics but also adhesives, printing inks and coatings used in the finishing of the final articles, as well as composite materials.

Content and Background

The objectives of the fact-finding missions were to gather information on the system of official controls along the FCM chain, in particular on the implementation of rules required by Regulation (EC) No 1935/2004 and further laid down in specific legislation, such as Regulation (EU) No 10/2011 on plastic FCMs and to identify examples of good practice, which could be mutually beneficial to Member States in addressing controls on FCMs.

The objective of the audits that followed, was specifically to evaluate the system in place for official controls regarding FCM. The scope was focused on materials covered by EU legislation subject to official controls.

A first series of missions/audits related to FCM had been carried out by the Commission services in 22 Member States, between 2007 and 2011[(3)]. The outcome at the time was that in many Member States, the implementation of controls had only just started and further efforts were needed to develop the control systems, such as the elaboration of specific guidelines, upgrading of laboratories, specific training etc. Moreover, the designation of competent authorities for the official controls was often not sufficiently clear, resulting in either a lack

(1) https://ec.europa.eu/food/system/files/2020-07/cs_fcm_eval_btsf_20190604_controls-sum.pdf

(2) https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/specific-eu-policy-initiatives/evaluation-and-revision_en

(3) Individual reports, see **Table 2**.

of, or an overlap in coverage of official controls. In addition, as the registration of FCM operators (producers and importers) was not mandatory under EU law, it was likely that not all FCM operators were on the radar of the official control services. There were, generally, no well-established risk-based official controls at FCM-manufacturing level, and further efforts were needed by Member States to focus also on controls at FCM users (food processors). Competent authority staff were often not sufficiently trained on specific FCM-related issues, such as assessments of the declaration of compliance (DoC), traceability systems and on good manufacturing practice (GMP) principles.

Why are FCMs regulated?

The FCM industry is a significant industry in the EU, with an estimated annual turnover of €100 billion.

Around 1,000 substances are authorised in the EU for the manufacture of plastic FCMs only. Before this authorisation, the European Food Safety Authority (EFSA) assesses each substance based on a number of requirements. The higher the migration into food, the greater the amount of data is required to evaluate the substance in the plastic FCM and its potential long-term health effects, such as genotoxicity, carcinogenicity and reproductive effects.

The estimated number of substances used in all FCM is ten times as high. Some estimates place the number of different substances possibly occurring in and relevant for FCM at 100,000, including non-intentionally added substances (NIAS).

The chemical interactions between FCM and food are highly complex and the possible migration of substances from the FCM into the food depends on a number of factors, mainly related to FCMs and food composition (fat, acid, moisture, dry, salt), environmental conditions and uses by end consumers (thermal stresses, from - 40 °C over + 300 °C, high pressure over 500 MPa, ionizations, mechanical stresses, long time of contact with FCMs and food).

The FCM Regulation

Regulation (EC) No 1935/2004 (the FCM Regulation) provides a harmonised legal EU framework for FCMs. It requires FCMs to be manufactured using GMP so that they do not endanger human health or bring about an unacceptable change in the composition or deterioration in the organoleptic properties of the food. It further provides the power to enact specific EU measures for specified materials and articles. The current Regulation lays down procedures for the authorisation of substances used to manufacture FCM, as well as rules on labelling, compliance documentation and on traceability. It also requires Member States to carry out official controls in order to enforce compliance with the Regulation and to lay down rules on sanctions applicable to infringements of the Regulation.

The form of controls may cover a wide range of different activities, from inspection of compliance statements (including DoC), supporting documentation including risk assessments through to physical sampling and analysis. In parallel to the controls, Member States must take all measures necessary to ensure that sanctions are implemented.

Since 2017, an evaluation has been underway at EU level[2] to assess whether the current EU legislative framework for FCM is fit for purpose and delivers as expected. It is assessing the overall effectiveness, efficiency, relevance, coherence and EU added value of the FCM Regulation. The evaluation covers the functioning of the FCM Regulation in its entirety and the rules and tools provided for by this legislation. The exercise evaluates how the approaches, procedures and processes established by the Regulation and implementation contribute to the main objectives of securing a high level of protection of human health as well as the effective functioning of the internal market for FCM. It includes the concepts and ways in which these measures regulate FCMs, including risk assessment and risk management processes, authorised lists of substances, document requirements, GMP, traceability and enforcement. It covers FCMs for which specific EU measures exist (EU harmonised FCMs) as well as FCMs for which no specific EU measures exist but may exist at national level, as set out in Article 6 of Regulation (EC) No 1935/2004.

New Official Control Regulation: requirements for FCM

The scope of the new Official Controls Regulation (OCR) now explicitly captures the business operators involved in the FCM chain: FCM operators are explicitly included.

Member States' competent authorities should take account of previous records on compliance as well as the reliability and results of businesses' own controls that have been performed by themselves, or by a third party at their request, including, where appropriate, private quality assurance schemes, for the purpose of ascertaining compliance.

Member States' competent authorities must draw up and keep up-to-date a list of FCM business operators. Where such a list or register already exists for other purposes, it may also be used for the purposes of this Regulation.

New rules concerning the accreditation of official control laboratories may affect their ability to undertake official controls on FCMs.

2. MAIN FINDINGS OF THE SERIES OF MISSIONS

2.1 National legislation and national guidelines

Many Member States have national legislation on a number of different FCMs including paper and board, metals and alloys, glass, coatings, silicones, rubbers, and printing inks, although these national provisions do not provide for specific measures for all FCMs[4].

2.2 Designation of competent authorities and resources for official controls

The designation of competent authorities including the National Reference Laboratories (NRLs) and other official laboratories in charge of FCM in the majority of the Member States visited allows official controls over all the actors of the FCM chain.

All the NRLs and other official control laboratories involved in official FCM analyses are accredited to ISO/IEC 17025. In the majority of the Member States the laboratories have the capability to provide reliable analytical results for a limited number of substances in

(4) https://publications.jrc.ec.europa.eu/repository/handle/JRC104198

comparison to the approximate 100,000 entering the FCMs composition.

The scope of accreditation of these NRLs to ISO/IEC 17025 varies between Member States. NRLs in Member States are organised in different ways. Some deal with FCM only partially (e.g. some single projects within five years), others are acting as "private bodies" (e.g. institutes of universities) mainly dealing with requests of private companies for whom they are able to perform various types of costly analyses which are paid directly by the industry.

Whilst some official laboratories are able to analyse a sufficient number of samples both from consumer outlets and directly from producers, others can only analyse a few samples due to less experience and lack of resources to cover the high costs of those analyses. Besides mandatory sampling (e.g. as required by Regulation (EC) No 284/2011 "Polyamide and melamine plastics imports from China", known as the "China-Measure") in many Member States routine analysis of samples is not of high priority or is not possible. While a number of substances are regulated through FCM legislation, in particular Regulation (EU) No 10/2011, most laboratories are not able to analyse them.

Many laboratories (also NRLs) are not able to analyse complex substances and, in general, often substances with specific migration limits. In addition, many laboratories are not able to analyse for presence of substances, which have not been specifically assessed by EFSA or authorised, such as NIAS or oligomers in plastics (polyamide oligomers), which are potentially dangerous components for the safety of the FCM.

Furthermore, there are no requirements for Member States to analyse a minimum number of samples/year or the substances which should be preferentially tested for. Therefore, in the majority of the Member States visited, official controls are able to focus only on a limited number of regulated substances and non-compliances are rarely detected outside the scope of Regulation (EU) No 284/2011.

2.3 Registration of FCM establishments

In the majority of the Member States visited, there is a system in place for the listing of FCM business operators that would enable inspectors to identify business operators for the purpose of official controls. However, the systems were not fully effective as lists were not regularly updated and there was no obligation, at the time of the 2018 audits, for the business operators, to register in any of the Member States visited. Thus, when a competent authority identified an unregistered business operator, there were no sanctions applicable.

In addition, at the time of the 2018 audits, some Member States did not require those companies producing or importing FCMs to officially register their business activity, which is a major obstacle to the implementation of official controls.

2.4 Organisation and scope of official controls

In the majority of the Member States visited, a risk-based plan, including inspections and sampling, manuals, guidelines and checklists available to the inspectors, facilitates that control activities are carried out in a uniform and systematic way. Participants in the 2019[(1)] BTSF workshop reported that these documents have substantially improved in all Member States over the past two years after the Commission launched the 2017 series of fact-finding missions. However, in the absence of sufficient technical knowledge/experience, inspectors

can easily overlook relevant aspects of official controls on FCM even when using comprehensive checklists; this, in turn, affects the capability to plan and organise controls on a risk-basis based on the degree and frequency of non-compliances.

In addition, in some Member States, competent authorities did not keep data regarding non-compliances. Inspectors did not systematically record non-compliances and, even when recorded, they did not systematically ask for their correction.

2.5 Implementation of official controls in Member States

Following informal discussions with control officers, there was the clear perception that FCM constitute a low-risk or, in any event, a low control priority, also due to the complexity of the subject, the lack of competence, the lack of analytical methods and their high costs. This perception may partially stem from the following: 1) adverse effects on human health may only occur in the longer term through repeated exposure and be due to a combined effect/sources, and 2) a false assumption that, as food is subject to tests "anyway", such testing would cover exposure/contamination from the food containers (FCMs).

Official controls could be much more efficient and effective if they are carried out by experienced and highly trained staff. Some Member States have already benefited from the experience shared during the series (in particular of the experience of the national experts). After having been visited, and in response to the fact-finding missions in 2017 and the 2017 BTSF workshop in Grange, concrete actions were implemented to improve and fine-tune official controls over FCM.

In some Member States there are dedicated teams for FCM inspections. It was evident that when inspectors had relevant qualifications and knowledge (e.g. chemistry), the quality of the controls carried out was significantly higher than in other instances. In particular, inspectors with relevant qualifications and knowledge know what to ask and what to look for during an official FCM control. Competent authorities acknowledged the relevance of staff with a background in chemistry, for an in-depth FCM controls on site. Generally, inspectors have a food/ HACCP background rather than materials chemistry.

In some Member States visited, the competent authority stated that in the course of FCM official controls, further details were investigated in the office with the help of more specialised experts (back-office). Those competent authorities explained that the training of inspectors was only effective to a certain extent (basic training on whether DoC was available and formally compliant). Indeed, for specific aspects of the FCM legislation, highly qualified experts are needed and it is not feasible to give all specific information to each inspector.

However, the perceived complexity of the subject of FCMs resulting in comprehensive legislation cannot be taken as a justification for limiting official controls. Indeed, there are examples of identified deficiencies during the fact-finding visits and audits that could be rectified by tailored but basic training:

- A team of two official inspectors, qualified as experts, asked the business operator for the DoC for a plastic product. They received an environmental statement instead of a DoC, that was assessed as fully satisfactory and in line with the requirements of Regulation

(EU) No 10/2011, even if it was an inappropriate document and irrelevant for the purposes of the official control of FCM. This highlights a lack of basic knowledge.

- The audit team examined a case of a documentary check of an imported FCM and observed that the relevant information such as DoC and supporting documents were provided. The analysis mentioned in supporting documents related to ceramic material whereas the actual import concerned a plastic item. The inspectors did not identify this discrepancy during the official control. Instead, the analytical certificate was assessed by the official control as fully satisfactory and in line with the required limits.
- In one Member State, the inspectors were not able to compare the formal points of the DoC according to the requirement of Annex IV to Regulation (EU) No 10/2011.
- The audit team found that, for the verification of the legal compliance of a particular FCM the inspectors used the wrong legal basis. They requested the conformity documents for a rubber FCM referring to Regulation (EU) No 10/2011 which concerns plastic and not rubber, also showing the lack of understanding the difference between plastic and rubber FCM..

To note that the non-conformities listed above were not detected by the regional and central competent authorities present during the inspections either, indicating that the problem is not restricted to individual inspectors but is a systemic issue.

- **Manufacturers and processors**

In all the Member States visited, the following checks were missing:

- An assessment of the supporting documentation relating to the completeness of laboratory results in matters of specific migration;
- An assessment of the supporting documentation relating to the completeness of laboratory results on organoleptic tests to demonstrate that the FCM does not change the composition of the food or cause a change in its organoleptic characteristics;
- An assessment of NIAS – e.g. impurities, reaction products and decomposition that can be formed during the processing from starting substances into final products. More generally, during the fact-finding missions and audits, no evidence was provided that the competent authorities had required an assessment of the manufacturing process of FCM by the operators, as required by EU legislation. This evaluation aims in fact to identify also the chemical by-products that may form during processing in order to assess the safety of the final FCM;
- A verification of the business operators' risk assessment, concerning substances not included in the Union list (see Article 5 of Regulation (EU) No 10/2011), as required under Article 19 of Regulation (EU) No 10/2011.
  This is not surprising in a situation where inspectors accept the mere presence of the DoC and supporting documentation without verifying the completeness of the information contained therein.

Concerning the checks on NIAS, the competent authorities stated that difficulties arise due partly to the fact that there are no EU standards that can be used to assist official staff during their controls.

GMP were controlled, based on official checklists (national), which reflect the basic requirements of Regulation (EC) No 2023/2006. Inspectors rely mainly on what the business operator provides them with during the inspection in terms of the manufacturing procedures and the operator's risk analysis. The Commission audit teams could not identify cases where risk analysis documents had been verified by official inspectors.

- **Importers / Wholesalers / Distributors / Retailers**

In some Member States visited, contrary to EU legislation, distributors asserted that they had no responsibility for providing the required documents to the competent authority since they act as intermediaries, even if they trade the products under their own brand name. No actions were taken by any of the competent authorities in those Member States to address these infringements of EU legislation.

The Commission audit teams noted that, in general, inspectors did not check for consistency between the labelling and the intended use of the FCM in accordance with the DoC, even if the distributor was responsible for the labelling of the final product.

In the majority of the Member States visited, the competent authorities stated that for products that arrive from other Member States, they would examine whether each specific FCM is in line with the legal requirements of that Member State (mutual recognition). In such cases, the central competent authorities stated that mutual recognition applied but evidence of compliance with the other MS rules was not provided.

Generally, at retail level, and although the inspectors identified a number of non-compliances in the DoC checked, inspection reports did not record these non-compliances and/or the associated corrective measures or other actions required.

- **Food business operators (FCM users)**

In some cases, inspectors checked the hazard analysis of the hazard analysis and critical control points (HACCP) plan of the food business operator (FBO) in relation to the FCM element. The inspectors limited their checks to a formal verification of the existence of a written plan, without verifying if the documents provided complied with the provisions described in the HACCP plan.

Rather, it was more often the case that inspectors limited themselves to the verification of the presence of a HACCP plan, rather than determining its fitness for purpose. Whether the DoC was in compliance or not with legal requirements was rarely considered during the inspection of the HACCP plan.

Concerning industrial food processing equipment coming into contact with food (e.g. rubber tubes, conveyor belts), a lack of control was equally identified: generally, controls were not traceable (no indication of what equipment was checked) and therefore it was impossible to determine on what types of material the controls focused, and to what extent.

2.6 National enforcement measures

Systems of national enforcement measures were in place. However, in the majority of the Member States visited, the systems of official controls were not fit to identify deficiencies and when non-compliances were observed, these were not followed by enforcement measures

and no penalties were imposed. Sanctions under Article 25 of Regulation (EC) No 1935/2004 are therefore not applied. All the Member States visited expressed concerns about their capability to enforce the FCM legislation adequately.

Regarding food commodities, and including in cases of manifest non-compliance (e.g. FCM's specific migration level exceedance, or incomplete or incorrect DoC), some Member States reported that enforcement is challenging as competent authorities may be required to demonstrate that the non-compliances result in the food being "unsafe" which may be difficult or impossible.

In 2017 and 2018, out of 258 FCM-related notifications through the rapid alert system for food and feed (RASFF), 82 were related to alerts (74 high migration values) and 97 to border rejections (90 from China). At the time of the 2018 audits, no Member State visited had withdrawn food commodities from the market due to non-compliant FCMs.. Furthermore, FBOs did not appear to consider the absence of the DoC, or its incorrectness, as a particular problem.

Member States attributed the difficulties in enforcing legislation primarily to the technical complexity of the FCM legislation (see paragraph 2.1), which, in order to be implemented and controlled properly, requires highly skilled staff in this specific sector as well as elevated costs for analyses where such methods of analysis actually exist..

Difficulties in enforcing EU legislation impact on the effectiveness of official controls in terms of raising/maintaining high levels of compliance. The reluctance to improve the existing system of official controls on FCM despite the shortcomings observed during the audit, underline that enforcement of FCM legislation is not a priority for the Member States.

Enforcement was also addressed at the 2019 BTSF workshop[1] and the participants suggested as a possible solution the inclusion of the "no documents – no market" approach in the FCM EU legislation as applied in the pesticides and chemicals areas, where the products need to be officially authorised before marketing. In such a scenario, and if the complete DoC is not available, the product should not be marketed and its use prohibited.

2.7 Challenges for competent authorities

NIAS: A major challenge identified by the CAs in the Member States visited is that the risk of a number of substances present in FCM is currently not being assessed by EFSA. In particular, this is the case for NIAS which are substances present either as impurities in the starting substances, or resulting from chemical reactions (such as decomposition products or by-products formed during the production process), that are present in the finished material. To some extent, the presence of NIAS in FCMs can be predicted, but this is only possible if for the intentionally added substances, any impurities in the starting substances and the processing conditions are known. For these reasons, it is important that complete information is provided by FCM manufacturers/processors to the CAs, and that there is good cooperation between scientific bodies and laboratories (public and private) throughout the Member States.

DoC: For stakeholders, this is a key instrument to demonstrate compliance with legal requirements for FCM. It is a legal declaration stating that an FCM meets the required standards, and which includes key information for the supply chain. According to the

framework Regulation, the DoC must accompany all harmonised FCMs with the relevant information, in order to allow for the manufacture and placing on the market of a safe final FCM and to facilitate reliable controls and traceability. In practice, however, DoCs are not always available for control/enforcement purposes, and, when they are, their quality (i.e. the accuracy and completeness) is not always sufficient to ensure that they are a reliable source of compliance documentation.

In the majority of the visited Member States, when the competent authority verified the presence of the DoC, the compliance level (i.e. presence of the DoC) was only around 60%. When the content of the DoC was properly examined with the required level of expertise, the compliance rates dropped to 10 – 30%.

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

Limited resources: The general limitation on resources that competent authorities face also affects controls on FCM. In some Member States, controls on FCM were carried out in "projects" (and this means "not regularly planned"). In other Member States, the number of available staff for conducting official controls on food (including FCM) was low in relation to the population and/or the number of operators. In the majority of the Member States visited, competent authorities consider FCM as a low-priority area and, therefore, allocated their resources accordingly.

Lack of validated laboratory test methods: Many requirements are defined but in reality laboratories are simply not able to check if legal requirements are fulfilled. For certain FCM, no validated methods are available, i.e. paper and cardboard, especially with respect to mineral oils in this kind of FCM, substances listed in Annex 1 of Regulation (EU) No 10/2011 and also for analysing NIAS. This is a burden for the official control laboratories, which need to develop laboratory methods regarding these materials in order to carry out the necessary analyses.

In addition, examination of real samples on a regular basis, to keep knowledge and expertise at laboratory level is important, especially in relation to new materials. Only with the experience of real samples, is it possible to improve knowledge in order to analyse the right parameters in the respective samples or choose the right samples from the market. For official laboratory staff, doing just paperwork (e.g. DoC check for formal issues) is not enough. In order to provide an adequate service, official laboratories must always be up to date, and keep pace with developments within the industry, which they are unable to do.

Lack of relevant expertise of inspectors: As already highlighted, the inspectors carrying out such controls have limited experience and expertise. This is also linked to the absence of, or limited, specific on-the-job training since the same inspectors usually carry out many other types of official controls, and together with the already limited number of FCM controls planned, have limited opportunities to develop familiarity with and expertise in these controls, and to acquire/maintain the levels of knowledge required. In some cases, staff from the official laboratories are also unable to assess the DoC and the supporting documentation.

RASFF notifications: For the respective competent authority (and also for the public laboratories writing expert opinions) it is not really clear in which cases a RASFF-report must be created. Some transmit data within the RASFF-system every time a given limit is exceeded (as serious risk), others inform only when limits are exceeded by factors ranging from ten to one hundred (because they consider FCMs as a low risk).

3. OVERALL OUTCOME OF THE SERIES OF MISSIONS

In general, competent authorities and official control laboratories in charge of FCM are designated in the Member States visited, and to a certain extent, competent authorities can identify the business operators involved in the FCM chain by way of a system for registration. The approaches taken to the organisation and implementation of official controls on FCM varied in the Member States visited.

In terms of effectiveness, official controls on FCM are challenging due to the very technical nature of the subject and the limited availability of suitable analytical methods allied with difficulties in ensuring that control staff possess the necessary level of technical knowledge and expertise. Risks to human health associated with FCM are perceived as relatively low by competent authorities. Controls in this area are not prioritised and, when undertaken are often rather superficial in nature, mainly focusing on verifying the presence of generic Declarations of Compliance rather than an in- depth assessment of the evidence supporting such declarations.

This, in combination with an absence of systems for hands-on training for control staff, leads to inspectors not being able to build up the requisite technical knowledge and therefore not being in a position to evaluate specific and relevant details of declarations of compliance and supporting documentation, as required by the legislation.

The audits found that inspectors could not reliably verify compliance with the general requirements of Regulation (EC) No 1935/2004 and/or with provisions covering the safety of FCM set out in other European legislation.

4. APPROACHES TOWARDS IMPROVING THE OFFICIAL CONTROL SYSTEMS

Besides fact-finding missions and audits, two BTSF workshops on FCM were held in 2017 and 2019(1) in which potential solutions for improving the official control systems in a cost-efficient manner, limiting any additional costs and resources, were discussed with the Member States.

4.1 Levels of the FCM official controls carried out in Member States

A possible approach to classifying the level of controls of FCMs was developed together with the Member States. It uses five levels (**0** – **4**) to describe to which extent FCMs are controlled and what an official control can do. The approach can be applied for individual inspectors as well as for an entire control system.

Using a scale of five levels, it is possible to describe what official controls can achieve, based on the available resources. This reflects the situation encountered during the fact-finding missions (2017) and the audits (2018). In this way it is easier to understand the requirements of FCM legislation and the current state of its implementation in the Member States.

In summary, **Level 0** means no controls and is not acceptable. **Level 1** represents checks only for the presence of documentation. **Level 2** requires the assessment of documentation. **Level 3** requires higher investments in highly qualified inspectors in the field of FCM. Finally, **Level 4** requires a high performing and capable laboratory with highly qualified staff.

The above would translate operationally as:

Level 1: *Presence of documents*

The competent authority assesses the presence of documents, but without performing any evaluation.

It could be easily and instantly applied by all inspectors; it has already the potential to improve the situation without additional costs.

Level 2: *Formal assessment of the DoC (Annex IV to Regulation (EU) No 10/2001) and a request for provision of the documents named or required in each point of the DoC.*

The competent authority is able to ask for the DoC and equivalent information in order to perform a basic check on the availability and compliance of the document.

It could be easily applied by all inspectors as it requires basic knowledge of FCM legislation.

Level 3: *The competent authority assesses supporting documentation underpinning the DoC.*

The competent authority has an in-depth knowledge of FCM production, knows the physical and chemical characteristics of the FCM under evaluation and is able to assess the content of a DoC. Furthermore, it can evaluate the supporting documentation needed to fully assess a DoC.

This requires, ideally, an expertise in chemistry, a good understanding of FCM legislation and of the different reasoning that can be used to demonstrate that a material is safe, the ability to obtain the supporting documentation, i.e. knowledge on what to ask, from whom, as well as the ability and resources to obtain it.

Level 4: *The competent authority verifies the correctness of the reasoning used in the supporting documentation.*

The competent authority performs specific analytical checks in order to verify the correctness of the information contained in the DoC or in the supporting documentation.

This requires a thorough understanding of the legislation, chemistry, toxicology, as well as of the material, its usage and risks that could have been introduced throughout the supply chain. It also requires the capability to perform analytical verifications in a laboratory. The competent authority will thus be able to independently verify the safety of the material rather than its compliance with individual specific provisions.

Towards Level 1 and 2: Basic knowledge of FCM legislation.

As observed during the fact-finding and audits, up to 60% of DoCs were incomplete which implies that the basic **Level I** was not or not correctly implemented. Given that this level does not require particular expertise, it is hard to argue that the problem with FCM controls is only the perceived complexity of the EU FCM legislation.

Moving to **Level 2**, which also do not require specific expertise over and beyond fairly basic training on FCM, would have the potential to increase the impact of FCM official controls. Inspectors of the competent authorities regularly inspect FBOs (meat and dairy producers are inspected several times a year). FBOs use FCMs and can therefore impose on their suppliers to present the right documents. In addition, if competent authorities would systematically require operators to make available a "formally" and complete DoC with all the relevant supporting documentation, it would improve the effectiveness of the whole control system along the FCM supply chain.

Towards Level 3: the 'Back office' approach

The 'back office' approach has proven to be very effective as well as efficient in some Member States. Indeed, potential risks with respect to the composition of the material were unlikely to be detected during the normal inspections.

This is because it is impractical to specifically train each individual inspector to become an FCM expert. Support by a 'back office' with experts, could be more affordable, realistic and effective (one expert is able to manage many different questions/requests from many inspectors).

Indeed, it remains challenging for an inspector to do a "risk assessment" of operators without understanding the situation of the specific FCM. An in depth assessment of the DoC and therefore of the assessment of the safety of the FCM inspected, cannot be done through any checklists as the main issue lies with inspectors being unable to properly use such checklists as they lack the necessary expertise and background. Such technical support could be provided effectively through a 'back office'. In addition, this facility would also be very useful in terms of planning and targeting of training as well as the controls themselves, given the nature of its work as well as its function as a repository for queries submitted to it.

Towards Level 4: National Reference Laboratories

NRLs have also an important role in the control of FCMs due to their expertise and knowledge with regard to the different materials that they are able to analyse. Especially NRLs must analyse routine samples on a regular basis.

The chemical part of a DoC and especially the supporting documents can usually not be assessed by inspectors. In contrast, experts in a FCM-laboratory could avail of the necessary experience to understand and evaluate such documents.

4.2 Self-regulation by industry

Business operators must comply with the legislation on FCM and, in so doing provide assurances on the safety of the final product. Business operators, in this context, include all actors along the supply chain, from those involved in the manufacture, processing and distribution of FCMs to importers as well as the users of the FCM such as FBOs.

Private standards are broadly used as part of private quality assurance systems in the food industry. Private standards for packaging materials are standards that manufacturers and suppliers of packaging are obliged to comply with by their customers. The driving force behind the creation and certification of these private standards is to reduce potential risks

(e.g. risks related to health, fraud, liability, traceability) and to protect business activities through the assurance of food safety, quality and liability.

5. MATTERS FOR CONSIDERATION BY EU MEMBER STATES

In order to improve official control systems, it should be clear how to implement official controls and what these controls entail, what can reasonably be implemented by inspectors in the field in terms of effective verification of compliance of FCMs, and the level of resource that Member States need to allocate to official controls in this specific area:

The minimum level required should be a basic official control able to detect DoC-related non-compliances, and which is currently often not the case. Member States should make efforts to ensure effective training for inspectors on FCM.

During official controls, competent authorities could usefully take advantage of the existence of private certification schemes, as most of those schemes also examine the compliance of the FCM produced or used in relation to existing legislative requirements.

Member States could also usefully consider how official laboratories can best be involved in this process. Each Member State could either have an official laboratory with methods for all the substances regulated by the legislation, or try to establish cooperation with other Member States in order to benefit from expertise and resources already available there.

6. ACTIONS TAKEN OR PLANNED BY THE COMMISSION SERVICES

- Two "BTSF – Workshop activities on strengthening Member States' response to Union audits" took place in Grange in 2017 and 2019. The discussions and findings of the last BTSF workshop (4 – 6 June 2019)(1) fed into the evaluation of FCM legislation. This is important when considering what improvements (if any) need to be made to existing legislation in order to facilitate enforcement as well as further harmonisation of FCMs at EU level;
- The Joint Research Centre of the European Commission has finalised and published a study to provide a comprehensive overview of the current situation concerning FCMs for which no specific measures are in place at EU level(4).
- The results of the implementation of testing pursuant to Commission Recommendation (EU) No 2019/794 (coordinated control plan to establish the prevalence of certain substances migrating from FCMs) examined in 2020, with a view to establishing further structured risk-based control plans at the EU level;
- An evaluation and revision of the EU legislation on FCMs which is in progress(2).

The Commission will host another BTSF workshop on FCM focused on the lack of accredited analytical methods and possible solutions.

The Commission will raise specific issues on the agenda of the FCM Expert Working Group and in the context of the revision of the EU FCM legislation, including the impact of the new OCR, e.g. registration of businesses and accreditation of official control laboratories, in order to support harmonised interpretation and implementation of these requirements.

TABLE 1:

List of Fact-Finding Missions (2017) and Audits (2018) carried out by the Commission services.

The individual reports, if published, are available at: https://ec.europa.eu/food/audits-analysis/audit_reports/ using the SANTE Reference Number.

Country	Dates and Activity*		SANTE Ref. No
Romania	21/02 – 01/03/2017	Fact-Finding Mission	2017-6091
Hungary	21/03 – 29/03/2017	Fact-Finding Mission	2017-6089
Germany	09/05 – 18/05/2017	Fact-Finding Mission	2017-6090
The Netherlands	06/06 – 14/06/2017	Fact-Finding Mission	2017-6088
Slovakia	23/01 – 31/01/2018	Audit	2018-6375
Lithuania	06/03 – 14/03/2018	Audit	2018-6374
Portugal	26/04 – 04/05/2018	Audit	2018-6376

**As indicated in the published report*

TABLE 2:

List of Missions and Audits carried out by the Commission services, between 2007 and 2011. The individual reports, if published, are available at: https://ec.europa.eu/food/audits-analysis/audit_reports/ using the SANTE Reference Number.

Country	Dates and Activity*		SANTE Ref. No
France	12/02 – 16/02/2007	Mission	2007-7187
The Netherlands	12/11 – 16/11/2007	Pilot Audit	2007-7219
Denmark	04/02 – 08/02/2008	Mission	2008-7832
Spain	07/04 – 11/04/2008	Mission	2008-7844
Slovakia	09/06 – 13/06/2008	Mission	2008-7850
Germany	15/09 – 19/09/2008	Mission	2008-7841
Finland	23/03 – 01/04/2009	Audit	2009-8149
Greece	30/03 – 03/04/2009	Audit	2009-8152
Lithuania	25/05 – 29/05/2009	Audit	2009-8159
Slovenia	05/10 – 13/10/2009	Audit	2009-8168
Portugal	26/10 – 04/11/2009	Mission	2009-8173
Latvia	02/11 – 11/11/2009	Audit	2009-8174
Romania	01/02 – 09/02/2010	Audit	2010-8573
Czech Republic	08/02 – 16/02/2010	Audit	2010-8576
Malta	08/02 – 12/02/2010	Audit	2010-8590
Poland	12/04 – 20/04/2010	Audit	2010-8578
Bulgaria	21/06 – 29/06/2010	Audit	2010-8584
Italy	04/10 – 12/10/2010	Audit	2010-8591
Austria	01/03 – 09/03/2011	Audit	2011-8997
Belgium	02/05 – 10/05/2011	Audit	2011-8998
Hungary	07/11 – 11/11/2011	Audit	2011-8999
Latvia	18/01 – 21/01/2011	Mission	2011-6000
Portugal	06/06 – 09/06/2011	Audit	2011-8996
Sweden	07/06 – 16/06/2011	Audit	2011-6001

**As indicated in the published report*

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 2017/625	OJ L 95, 7.4.2017, p. 1–142	Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)Text with EEA relevance.

Reg. 1935/2004	OJ L 338, 13.11.2004, p. 4-17	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
Reg. 2023/2006	OJ L 384, 29.12.2006, p. 7578	Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food
Reg. 10/2011	OJ L 12, 15.1.2011, p. 1-89	Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food

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