



# BTSF Workshop on Food Contact Materials

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## LEGAL NOTICE

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## Executive summary

The workshop "*Better Training for Safer Food – Training activities on strengthening Member States' response to Union audits*" took place from 4 to 6 June 2019 in Grange, Ireland. It was attended by policy and enforcement officials from 26 Member States, Iceland and Switzerland and presenters from the Joint Research Centre, a food business operator, a consultancy working on food contact materials (FCM) and a private standard setting / owning / inspecting body. The workshop focussed on official controls of FCMs.

The workshop was organised as part of the FCM project of Directorate F to present the findings and conclusions of fact-finding missions and audits, which were carried out in Member States in 2017 and 2018 in close co-operation and jointly by Units F1 and E2 as well as Member States' experts. The purpose of the fact-finding missions / audits was to gather information on the system of official controls and practical implementation of rules on FCMs as well as identifying good practices.

The objectives of the workshop were to discuss the findings and conclusions and for Member States to take ownership of these findings; to identify and discuss weaknesses and recurring problems, with the aim of identifying possible solutions at Member State and EU level and; to gain an understanding of good practices in the EU and how these may be adopted in Member States' control systems considering, in particular, the new obligations regarding the implementation of the new Official Control Regulation (OCR).

Overall, the workshop identified common problems and challenges in the control of FCM and allowed participants to share experiences and gain knowledge on these matters. It enabled participants to discuss best practices with peers from other Member States and helped to identify approaches, options and tools for implementing future cost-effective official control systems regarding, in particular, documentary controls on Good Manufacturing Practices (GMP) to verify compliance with applicable FCM legislation. Issues with the current legislation that present barriers to the effectiveness of FCM controls were also discussed and which may need to be addressed at policy level.

The outcome of this workshop is the result of a unique co-operation between Unit F1, Unit E2 and numerous high level experts of the Member States and related organisations. The information acquired will be disseminated across each participant, with a view to implementing the possible solutions with respect to enforcement activities. It is the aim to hold a workshop in the future to discuss and review the effectiveness of any follow-up action taken by Member States. The findings of the workshop will also be used to feed into the Commission's evaluation on the functioning of the current FCM legislation.

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## 1 INTRODUCTION

Food Contact Materials (FCMs) are stated in EU legislation as 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, tableware and items used in professional food manufacturing, preparation, storage and distribution.

Regulation (EC) No 1935/2004 of the European Parliament and of the Council<sup>1</sup> provides a harmonised legal EU framework for FCMs. It sets out the general principles of safety and inertness for all FCMs and further provides the power to enact specific EU measures for specified materials and articles. A series of measures relating to specific materials and substances have been established within the legal framework of Regulation (EC) No 1935/2004, comprising largely legislation on plastic FCMs.

The EU legislation also lays down rules on Good Manufacturing Practices (GMP)<sup>2</sup>, labelling, traceability, compliance documentation for FCMs regulated by specific EU measures and on official controls, which Member States are required to undertake. The form of controls may cover a wide range of different activities, from inspection of compliance statements, 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.

A workshop chaired by the Commission took place previously in 2017 and was attended by 38 FCM policy and enforcement experts across 24 Member States, Norway, Iceland and two invited experts. During this workshop, participants discussed safety aspects of FCMs, challenges of daily FCM laboratory work and four FCM fact-finding missions conducted that year by Directorate F. Working group sessions with subgroups were conducted to discuss official controls on FCM in Member States and options to improve control systems.

The workshop in June 2019 was organised by Directorate F, Unit F1 in close cooperation with SANTE E2, as a follow-up to both the fact-finding missions in 2017 as well as three audits on FCMs carried out in 2018. The workshop was organised to feedback and disseminate knowledge gathered during the missions and bring together inspectors and policy officials in order to gather information on the practical implementation of FCM controls as well as to share ideas and best practices. In addition to this advanced learning experience, the aim of the workshop was also to identify proposals for future actions and to feed into the Commission's evaluation of the current FCM legislation<sup>3</sup>.

## 2 BACKGROUND TO ACTIVITIES OF DIRECTORATE F

Directorate F (former Food and Veterinary Office) performed eighteen missions on FCM between 2007 and 2010. At the time of these missions, the implementation of official controls on FCM in many Member States had not long started. Further efforts needed to be made to develop the control system, such as the elaboration of specific guidelines, upgrading of laboratories, specific training etc. and, therefore, a series of recommendations were made.

In 2016, Directorate F developed a project that was rolled out the following year with four fact-finding missions (to DE, HU, NL, RO) which was extended in 2018 with three additional audits (to SK, LT and PT) concerning controls of FCMs. The objectives of the series of fact-finding missions were to:

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<sup>1</sup> <https://eur-lex.europa.eu/eli/reg/2004/1935/oj>

<sup>2</sup> <https://eur-lex.europa.eu/eli/reg/2006/2023/oj>

<sup>3</sup> [https://ec.europa.eu/food/safety/chemical\\_safety/food\\_contact\\_materials/evaluation\\_en](https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/evaluation_en)

- Gather information on the system of official controls along the FCM chain;
- Gather information on the practical implementation of rules described in Regulation (EC) No 1935/2004 on FCMs and specific measures made under it;
- Identify examples of good practice which could be helpful to other Member States in addressing controls on the FCM chain.

While the objective of the series of audits was:

- Evaluate the system in place for official controls regarding FCM.

### **3 OBJECTIVES AND FORMAT OF THE WORKSHOP**

The workshop deviated from the usual BTSF training where knowledge is imparted from lecturer to participant. Participants with experience and knowledge on the policy and enforcement of FCMs were invited to share experiences and ideas during the workshops and plenary sessions in order to learn from one another.

The intention of the workshop was to reflect on findings and discuss and provide approaches, options and tools for implementing future cost-effective official control systems in particular for documentary controls and controls on GMP to verify compliance with applicable FCM legislation. The workshop sought to identify the needs and potential shortcomings, allowing the participants to gain knowledge on these matters and to discuss best practices with peers from other Member States, in order to identify areas where legislative change could usefully be considered, how to implement such practices, as well as any perceived barriers.

Specifically, the objectives of the workshop were to enable participants and their respective Member States to:

- A. Take ownership of the findings and conclusions of the mission reports and overview reports and use them to improve their official control activities;*
- B. Gain an understanding of good practices in the EU and how these may be adopted in their own control systems;*
- C. Be able to identify and discuss weaknesses and recurring problems in their own Member State, as well as across Member States, with the aim of identifying possible solutions both at Member State and EU level.*
- D. Disseminate the findings of the workshop as relevant and implement the possible solutions with respect to enforcement activities carried out in the Member States with a future follow-up to ensure that Member States have taken action.*

A series of presentations were given during the three days, followed by Working Group activities.

### **4 SUMMARY OF INFORMATION PRESENTED AND DISCUSSED**

Altogether, 12 presentations were provided. In addition to those given by DG SANTE Directorate F on the conclusions, good practices and best practices from the fact-finding missions and audits, presentations were given on the possibility of establishing an enforcement platform and on the impact of the new Official Food and Feed Control Regulation (EU) 2017/625<sup>4</sup>. A number of

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<sup>4</sup> <http://data.europa.eu/eli/reg/2017/625/oj>

presentations were also given on control activities of Member States, compliance work of industry and private standards setting. All the presentations are available on the BTSF website<sup>5</sup>.

The following summarises the **key messages from the presentations**.

#### **4.1 PRESENTATIONS ON PRELIMINARY OVERALL CONCLUSIONS OF THE MISSIONS PERFORMED BY DIRECTORATE F CONCERNING IMPLEMENTATION OF CONTROLS IN MEMBER STATES**

- Official controls on FCMs in Member States are in general weak, not sufficiently effective and considered as a low priority.
- In general, few or no controls leads to a lack of findings, which in turn make it impossible to identify any risk. This, in turn, hampers risk-based controls and leads to a low prioritisation and fewer controls.
- Where controls are carried out, they are often limited to the verification of the presence of the declarations of compliance (DoC). Inspectors rarely have the resources or expertise to verify the information on the DoC by checking, for example, the supporting documentation or by assessing the consistency between the DoC and labelling.
- Competent authorities and official control laboratories in charge of FCMs are designated in the Member States visited. The Competent Authorities can only partly identify the business operators involved in the FCM chain.
- Underlying problems identified include:
  - Lack of regular dedicated inspections;
  - Lack of expertise and experience at the front-line control level;
  - Inability to identify all relevant business operators;
  - Lack of comprehensive checklists;
  - Lack of guidance documentation, including on the evaluation of DoCs;
  - Lack of effective training for inspectors;
  - Laboratories have neither the resources nor the ability to perform analytical checks on samples not foreseen by established control plans;
  - Enforcement measures and/or sanctions are not systematically imposed ;
  - Poor *documentation of controls* and few records of cases of non-compliance hampers future risk-based planning;
  - Industrial equipment is often overlooked during official controls.
- Inspectors also struggle to establish compliance with FCM legislation, in particular regarding Article 3 of Regulation (EC) No 1935/2004 in the absence of specific rules. Certain aspects of the legislation addressed at the EU level, including the risk assessment, risk management and subsequent enforcement of Non-Intentionally Added Substances (NIAS) are difficult even for experts.
- Overall, the current systems of official controls cannot adequately or fully enforce the requirements of the legislation although this does not imply that FCMs are unsafe.

Based on the findings of the audit teams and on the following first workshop, an approach to classifying the level of controls of FCMs was developed. It uses simple levels (I – IV) to describe to which extent FCM are controlled and what an official control can do. The approach can be applied at

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<sup>5</sup> <https://eu.eventscloud.com/ehome/200189163>

the level of individual inspectors as well as the entire control system. During the first workshop participants were asked to propose a name for the approach. After no name was proposed, it was decided to call it the "No-Name" approach. During the last workshop participants agreed to call the "No Name" approach in the future "**Control Aptitude Levels**" or "**CAL**".

### **Control Aptitude Levels – CAL**

The CAL covers 5 levels. **Level 0** means no controls and is not acceptable. **Level 1** represents checks only for the presence of documentation and could be easily and instantly applied by all inspectors; it has already the potential to improve the situation without additional costs. **Level 2** requires the assessments of documentation and implies some investments in knowledgeable and trained inspectors. **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.

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#### **CAL 0:** *No controls*

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#### **CAL 1:** *Presence of documents*

The Competent Authority assesses the presence of documents 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.*

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#### **CAL 2:** *Formal assessment of DoC (Annex IV Regulation (EU) Nr 10/2001) and request of the documents named or required for each point of the DoC.*

The Competent Authority is able to ask for DoC and equivalent information in order to perform a basis 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.*

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#### **CAL 3:** *The Competent Authority assesses supporting documentation to see whether it could support the statement of compliance.*

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 request and 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.*

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#### **CAL 4:** *The Competent Authority verifies the correctness of the reasoning used in the supporting documentation.*

The Competent Authority requires and performs specific analytical checks in order to verify the correctness of the DoC or of 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 establish the safety of the material rather than its compliance with individual specific provisions.*

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The fact that up to 70% of DoCs were incomplete as observed during the fact-finding and audits demonstrates how the CAL approach could improve the performance of Member States' official controls.

Application of **Level 2** has the potential to increase the impact of official FCM controls because inspectors from CAs regularly inspect FBOs (meat and dairy producers are inspected many times per year). FBOs are FCM users and can therefore dictate the need for the presence of the right documents to their suppliers, applying the "No Paper No Market" approach.

**A practical example is illustrated as follows:** A producer of FCMs gives an incomplete DoC, with generic statements meaning that he is not bound by any obligation. He is only responsible for what he has declared, which in practice equates to almost nothing. Consequently, no Supporting Documentation is available because the producer does not need other proof in order to fill-in a very weak DoC.

What happens if the FBO asks for (or he is obliged by CAs to ask for) a "formally" complete DoC?

The FCM producer has to fill-in all the requirements of the DoC, all the legal points as required by Annex IV Reg 10/20011 have to be addressed and he/ she has to sign such a DoC and, therefore, he/ she is legally responsible for each point of the DoC. Consequently, the producer is legally bound by the obligation he/ she signed and must be able to provide the pertinent Supporting Documentation (otherwise he/ she would not be able to fill-in the points of the DoC). Consequently, the scope for any lack of clarity remains small.

This indicates that the CAs should be able to detect DoCs "formally" incomplete and be able to request corrective actions immediately.

Therefore, asking for "formally" complete DoC means to oblige the producers to produce also the right documentation and to make available also all the relevant information (SD). If this approach is applied along the FCM supply chain, it will improve the whole system and for CAs it would require only a better use of available resources.

#### **4.2 PRESENTATION BY THE JRC ON THE RELEVANCE OF AN FCM ENFORCEMENT PLATFORM**

Discussion on the potential need for an enforcement platform has evolved from discussions through the EU Reference Laboratory (EU-RL)/ National Reference Laboratory (NRL) network for example, if there is a lack of harmonised kitchenware test conditions, test results may vary. Similar initiatives on the DoC have been led by Switzerland and Germany.

Exchange of information on enforcement is generally insufficient in the context of the Rapid Alert System for Food and Feed (RASFF) notifications as it focuses only on non-compliance and does not cover issues that may be challenging for controls.

In general, Member States support such an initiative to exchange information and share common practices to improve efficiency and consistency of enforcement. The topics that could be covered include a wide range of enforcement issues such as inspections, types of businesses, inspection planning, DoC, supporting documentation, inspection reports, GMP, training and guidance for inspectors, sampling, analysis, inspection reports, determination of compliance, follow-up actions and sanctions.

Understanding the structure and organisation of enforcement bodies, which can be complex and differ significantly amongst Member States, can also help.

It remains to be decided how to best implement such a platform and who can lead on it, taking into account the required resources.

#### **4.3 PRESENTATION BY DIRECTORATE F ON IMPACT OF OFFICIAL CONTROLS REGULATION ON FCMs**

Regulation (EU) 2017/625 – the Official Control Regulation ('OCR') entered into force in 2017, although the majority of articles apply as from 14 December 2019, including those on planning and reporting (Articles 109 – 115) and enforcement action (Articles 137 – 141).



The scope of the new Regulation now explicitly covers the manufacture and use of FCMs.

The Regulation obliges Competent Authorities to perform regular controls on all operators on a risk basis and with appropriate frequency. Controls should be undertaken on products, substances and materials that may influence food safety, including food processing equipment and packaging. Official controls should include a verification of compliance already established by the business operators and procedures on GMP.

Member States' Competent Authorities should take account of previous records on compliance as well as the reliability and results of businesses' own controls or controls by a third party including, when appropriate, private quality assurance schemes in order to ascertain compliance.

Control procedures must be documented, reporting the method applied, the outcome of the controls and whether appropriate actions were taken. Controls must be reported each year to the Commission to ensure uniform conditions for implementation of the Regulation and to facilitate the collection and transmission of data and the subsequent compilation of such data into Union-wide statistics.

Member States' Competent Authorities must draw up and keep up-to-date a list of operators. Where such a list or register already exists for other purposes, it may be integrated 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.

#### **4.4 MEMBER STATES' EXPERIENCES AS REGARDS CONTROLS OF FCMs**

Five Member States provided an overview of their experiences with the implementation of controls on different types of business operators.

##### **I) Slovakia: overview of controls of FCM producers**

Although there is no mandatory registration of FCM producers, information is shared across government departments in order to identify different types of FCM producers. Controls of FCM producers are carried out under their multi-annual national control plan, every 1 – 3 years depending on previous results. Approximately five controls per year on average had been carried out during the last three years before the workshop. This translates into a control frequency of 5% meaning that each producer is inspected every 20 years (it is estimated that 100 FCM producers are operating in Slovakia).

Planning is undertaken at the regional level where staff has annual training with expertise and technical support from back office/ NRL staff. Sources of information for preparing the controls include FCM legislation, including Regulation (EC) No 2023/2006 on GMP and various ISO norms. Specific guidance for both inspectors and for industry exists. Prior to the controls, a questionnaire is sent to the FCM producer with a request for relevant documentation.

A check-list is available for inspectors to help perform the controls, regarding DoC and supporting documentation for input materials and final FCM as well as traceability and training of staff. One sample is also taken for analysis by the NRL during each inspection.

The overall assessment of GMP of the controlled business operator is classified in accordance with the findings - safe (no non-compliance), safe with comments (requiring corrective action), conditionally safe (requiring more significant corrective action) or dangerous (GMP not in place).

##### **II) Lithuania: overview of controls of importers, wholesalers, distributors and retailers**

Competent Authorities include the Ministry of Health, which develops FCM policy and establishes mandatory safety requirements; the State Food and Veterinary Service (SFVS), which performs the official controls and the National Public Health Surveillance Laboratory, which acts as the NRL.

SFVS is divided into 14 departments, including the food department, which prepares FCM control plans, coordinates FCM controls, maintains an oversight of FCM businesses and training of inspectors. A further 52 structural units (market controls) and 12 border posts (import controls) exist to implement the control plans. A significant number of staff have been trained on FCMs including 155 in 2018.

In addition to control of FCMs based on EU legislation, Lithuania has national specific legislation (Hygiene Norm HN 16:2011), applicable to manufacturers and importers of non-EU FCMs. National legislation covers paper and board, migration of metals and registration of businesses (including manufacturers, suppliers and importers but excluding retailers). Controls are carried out only where specific rules exist.

Official controls are carried out routinely according to the multi-annual national control plan (MANCP) or on a random basis, based on consumer complaints, information from public authorities or RASFF notifications.

Since 2015, uniform standardised controls procedures and processes have been applied. Instructions and individual checklists are prepared in advance for inspectors, depending on the type of business or FCM to be inspected. Data is stored on the registered business operators, including inspection reports and supporting documentation, sampling non-compliances and any sanctions carried out. Risk based controls are carried out according to factors such as type of FCM, country of origin, history of non-compliance based on RASFF notifications and on the previous year's results – consequently reflecting the frequency of controls (high risk twice a year, medium risk once a year and low risk once every three years).

Guidance to inspectors includes information on which check-list to use according to the type of business operator, how to control labelling, traceability, DoC and supporting documentation and how samples should be taken and sent to the laboratory. Sampling can be performed at all stages of the FCM supply chain although priority is given in particular to importers and suppliers. The Lithuanian MANCP foresees around 50 FCM samples. Sampling is carried out for organoleptic properties as well as known chemical risks. Non-compliance in 2018 was 8%.

Many challenges for the official control of FCMs have been identified. These include lack of priority, lack of specific rules, lack of knowledge and experience amongst inspectors, limited laboratory facilities, lack of information in the supply chain and incomplete DoCs, as well as limited knowledge of some business operators, particularly importers and suppliers. New types of material on the market also provide a challenge, such as stone, straw and leaves.

### **III) Italy: overview of controls of users (food business operators)**

The Italian Competent Authorities have a database of registered food business operators (FBOs). For FCM purposes, FBOs are classified as either those who only use FCMs (e.g. for processing or packaging of food) or intermediate material manufactures (e.g. bottle blowing/ inflating).

Control is divided into three levels – the Ministry of Health, responsible for the national plan and internal audits on Regional Competent Authorities; a Working Group composed of regions and the Ministry working on a regional plan and internal audits of Local Competent Authorities and; Local Health Units in charge of local planning and official control of FBOs. Laboratory resources are available at the central and regional levels.

Local Competent Authorities comprise inspectors, some trained on FCMs but rarely on the evaluation of the contents of the DoC or supporting documentation. Back-office expertise is available (e.g. chemists).

Controls take place in the form of an inspection with no notice given in advance or in an audit based on previous information. The national official control program concerns only sampling of FCM, where around 1800 analytical results are generated on FCM per year. The number of samples taken depend on the population size of each region in Italy.

If the FBO is a final user, authorities control whether the labelling of FCM is correct and check the documentation for intended use, traceability of FCM (in case of alert) and correct uses of the FCM inside the food process room (temperature, composition of food, pH, etc.). If the FBO also transforms the material, the process (temperature, time, hygiene) is also controlled.

The Working Group composed of regions and the Ministry is currently producing a document for harmonisation of official controls on FCMs in Italy.

#### IV) Romania: overview of a **back office approach**

The responsibility for official control of FCMs including imports lies with the Ministry of Health, following a cooperation protocol with the National Sanitary Veterinary and Food Safety Authority. The Ministry of Health is responsible for the legislation and inspections through the general Directorate of Nursing and Public Health (GDNPH) and the State Sanitary Inspection (SSI). The latter is, in turn, divided into different county public health directorates (42) employing chemists, food engineers and lawyers who have responsibility in other fields as well.

In addition, the National Public Health Institute (NPHI), which has national and regional centres, develops and coordinates the national monitoring programs including on FCMs. The regional centre in Bucharest functions as the NRL for FCMs, with an additional laboratory accredited for analysis of FCM plastic samples.

The Ministry of Health and NPHI develop an inspection plan together, tailored by each county public health directorate depending on their individual circumstances and experiences. New business operators, non-conformities, exporters (e.g. ceramics), RASFF data and customer complaints are used as the basis for prioritising inspections.

Inspectors have a relevant degree and basic training. Specialised training takes place at the local level and is organised by the Ministry of Health.

Inspections take place in four phases – an opening meeting followed by a visit of the premises and selection of controls to be made; thirdly, in the case of FCMs, a study of DoC, labelling, supporting documentation, sub-contracting documents, GMP and HACCP is conducted and finally a closing meeting is organized to summarise the main points and decide what follow-up action needs to be taken. A report is made with conclusions and deadlines for action and the business operator has 15 days to respond. Inspectors also control manufacturers for GMP.

Where non-compliances are identified, warnings, fines, withdrawal and / or recall from the market or prohibitions on FCM products are all options available to the authorities. A RASFF may also be raised.

The main difficulties highlighted by Romania are a lack of laboratories with accredited methods, insufficient inspectors with FCM training and, in general, insufficient resources to carry out proper sampling and analysis activities.

#### V) Germany: overview of practical implementation of the **'No Name Approach'** FCM controls in Baden-Württemberg (Germany).

During the Commission's fact-finding missions, an approach was formulated to quickly describe the level of the official controls in a Member State, the 'No Name Approach' (see section 4.1 – The 'No Name Approach', now CAL). Subsequent to the fact-finding mission carried out in Germany, the federal state (Bundesland) of Baden-Württemberg trialled the application of this approach.

The overview highlighted the complex structure of the German control system which includes 16 federal states (Bundesländer), 429 urban areas and districts, each containing a Competent Authority responsible for food – 44 of which are in Baden-Württemberg – which, in turn, is split into four separate chemical and veterinary investigation offices. In Baden-Württemberg, only one central laboratory exists for FCM analysis responsible in this field for whole of Baden-Württemberg. Throughout the other federal states in Germany, there are approximately 10 further labs responsible for FCM analysis.

The Commission's fact-finding visit raised awareness of FCMs amongst the local Competent Authorities in Baden-Württemberg, who engaged in discussions with the responsible ministry on how to improve the situation. Together with the LKL (State Control Team – a task force of experts with different relevant professional backgrounds), a detailed check-list was created to gather all relevant information on large FCM producers. Orders were also created to establish a first list of FCM businesses originating from the 44 Competent Authority districts and to develop and perform training courses on conformity checks (corresponding to **Levels I and II** of the CAL), based on a checklist for formal checks of the DoC.

The training courses were well received and were found to be helpful to simplify formal checks. In some districts, Competent Authorities have since set up FCM control teams and dialogue has been initiated with the Bundesländer. However, some inspectors, particularly food inspectors, have also stated that they find FCM controls complex and considered as a low priority. Specialized public "FCM-Labs" are urgently needed to verify statements given in DoCs and SDs as well as to perform special analysis (e.g. oligomers) and implement new methods.

#### **4.5 BUSINESS OPERATOR COMPLIANCE WORK AND PRIVATE STANDARDS FOR FCMs**

- **A food business operator gave its perspective on self-controls**

This business operator has 1800 employees and supplies meat products in Italy, Europe and Third Countries. It is therefore a user of FCMs such as plastic and cellulose casings, plastic trays, labels, food processing equipment and gloves.

It described its compliance activities with EU and Italian FCM legislation including purchase specifications (technical data sheet and regulatory references), analysis on overall migration, specific migration and an annual packaging analysis plan.

It also described its requirements from suppliers, including a data sheet, reports on overall and specific migration as well as the DoCs for both plastic and non-plastic FCMs.

Audits are performed on its suppliers according to a risk analysis.

HACCP is also used by the business operator to ensure compliance with the process and usage conditions of the packaging, including time and temperature conditions, sealing, vacuum welding, sterilisation and pasteurisation.

Corrective actions that could take place in case the documentation from the supplier is not compliant include blocking of the batch, request for updated documentation and self-analysis. Eventually, suspension of the supplier may be executed.

Requirements from the business' customers include compliance with relevant legislation, process and usage conditions and specific requests such as absence of bisphenol A, reduction or exclusion

of mineral oils or presence of a functional barrier. In 2018, there were 62 audits from customers as well as certification providers.

- **A private standard setting and inspection body (BRCGS) described the checks that they carry out.**

The company operates globally and has a standard specifically for the manufacture of food packaging materials. This covers hazard and risk management, site standards, product and process control, personnel and traded goods.

The audit process carried out by BRC categorises products according to the type of material and process involved (e.g. paper making and conversion, flexible plastic manufacturing, print process etc.). Audits are either announced or unannounced every 12 months.

Approximately 30% of FCM producers in the EU are inspected and certified on processes (GMP), although BRC does not certify materials and does not go into depth on the technical details of FCM. In order to gain accredited certification, all identified non-conformities must be resolved and an audit report produced.

## **5 OUTPUTS FROM GROUP ACTIVITIES**

After the presentations, participants worked in five groups to discuss and address three different FCM related themes on enforcement:

### **5.1 PLANNING OF RISK BASED CONTROLS**

Two groups discussed what factors should be taken into consideration in the planning of risk-based controls. The following factors were discussed:

- Origin, including import from third countries
- Turnover and volume of FCM on the market
- Type of material
- Type of consumer that may use the FCM (infants and children)
- Past records and history of compliance of the business operator and/ or the product
- Type of activity of the business operator
- Existence of specific legislation and/or recommendations

The groups also discussed where they felt the information should originate from in order to help perform controls:

- Results from official controls and inspections
- Rapid Alert System for Food and Feed (RASFF) and Administrative Assistance and Cooperation System (AAC)
- Registration of businesses
- Consumer complaints
- Discussions from the Member States' Expert Working Group or EU-RL/ NRL meetings
- Information from business operators, in particular on the use of new materials
- Scientific reports
- News and media reports

The groups considered what proportion of each type of control should be applied when inspections are carried out. There was a consensus that there should always be documentary checks. It was

suggested that physical checks should be performed on all new registered business operators and that, overall, should make up a minimum of 10% of controls although this would depend on the capacity of laboratories and on resources. The type of control would also depend on the activity of the business (e.g. manufacturer, retailer).

Finally, the groups considered that uniform application of risk-based planning can be extended across the EU with the aid of more harmonised legislation, guidance with criteria for planning, training, platforms for exchange of views and joint projects. It was recalled that the recently published Commission Recommendation (EU) 2019/794 on a coordinated control plan with a view to establishing the prevalence of certain substances migrating from FCMs<sup>6</sup> was a good example and may provide a platform to build on.

## **5.2 THE CAL APPROACH (FORMER 'NO NAME APPROACH')**

Two other groups discussed the CAL Approach' and agreed that currently the majority of controls are restricted to **Level I** i.e. checking for the presence of documentation only. Some felt that controls were on a higher level but depending on the stage of the supply chain (producer, importer, retailer) and the type of material and substances for which analysis might be needed (i.e. as to whether to progress to **Level IV**).

Participants felt that each level of control can ensure some level of health protection but that for **Levels I and II**, the impact is much lower compared with **Levels III and IV**, where consumer protection is more enhanced as more detailed analysis of documentation and verification of results is carried out. Nevertheless, the presence of an inspector on the ground is considered important. Again, this depends on the type of material and on the labelling for the consumer giving instructions for safe use.

Regarding expertise, it was felt that **Levels I and II** need an inspector with a basic level of training, ideally with an interest in the area of FCM and understanding of the legislation. However, it was felt that this is still often challenging for FCMs which do not have specific rules. By contrast, **Levels III and IV** require a technical expert, with training on chemistry or related subject, with a specialised knowledge of the FCM area and with a more concrete understanding of the legislation and its application. **Level IV** may also require a toxicological background or similar.

Finally, participants discussed how to progress controls to higher levels. They agreed that it was a question of time as well as resources. Systems for exchange of data including risk assessments, ability to collaborate, consistency of approach, of implementation, experience of staff, guidance and training on practical issues were all considered important factors.

## **5.3 FOLLOW UP AND SANCTIONS**

The final group discussed the follow-up and sanctions concerning enforcement of FCM legislation.

They were first asked to consider how they perceive the current situation. They concluded that the situation varies across the EU and it is up to Member States to decide how they enforce requirements. In general, however, the type or severity of non-compliance dictates the level of action although perception of the non-compliance may be different across Member States. The level of deterrents is not necessarily the same as, for example, since the size of the business does not determine the level of the fine, big business with a large turnover could accept a fine without taking any correcting action. Defending decisions in court are also perceived as very difficult in the absence

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<sup>6</sup> <http://data.europa.eu/eli/reco/2019/794/oj>

of harmonised and specific regulations to refer to. The absence of such rules means that enforcement is weakened, as authorities do not take cases to court, which they may otherwise be merited with clear specific rules and sufficient resources.

Participants agreed that varied responses and actions to non-compliance could lead to business operators not efficiently carrying out appropriate changes to their operations. This could result in more unsafe materials entering the market, in particular from one Member State into another if rules were applied differently. Lack of appropriate action could also result in riskier materials being used or advertised online in other Member States.

The group identified several areas where improvements could be realised:

- Sharing of information between MSs with regards to enforcement of harmonised materials and articles. Further consideration is required for FCMs without specific measures as more flexibility may be required with potential enforcement measures.
- The need for a DoC for FCMs without specific measures should be considered.
- Different levels of approach could be implemented, for example:
  - 1<sup>st</sup> level of approach may consist of a warning letter to business operator;
  - 2<sup>nd</sup> level may consist of issuing a follow-up letter with an obligation for the business operator to take corrective action and comply with the current Regulation or conditions. This should be followed up with an inspection;
  - 3<sup>rd</sup> level may consist of penalties and/or court action.

At the EU level, group participants recommended guidance to be developed, covering potential solutions to carrying out actions/sanctions, which could also be applicable for national legislation. The guidance could refer to specific examples to allow Member States to consider what actions/sanctions are proportionate and appropriate.

## 6 CONCLUSIONS

The workshop was successful in drawing together experts involved in FCM policy and in FCMs inspections in order to document **key challenges** concerning control of FCMs. The basic finding concerning the inspection and control of FCMs in Member States is that they are not a priority and are weak when undertaken, often only comprising of verification of the presence of DoC. Resource is one key issue. FCMs are a complex area, requiring Member States' controls bodies to have personnel with expertise and experience in understanding a number of key subject areas including manufacturing processes, chemistry, toxicology and risk assessment. Often inspectors lack such expertise and experience and instead are more geared to controls of foodstuffs, hygiene or HACCP requirements. A lack of controls also implies a lack of findings by Competent Authorities and a failure to identify potential problems. This in turn hinders the ability to prioritise FCM controls as risks may not be identified.

A number of individual problems were identified and discussed as being prohibitive for carrying out controls. First, there is a lack of regular dedicated inspections, in part because FCM controls are not considered a priority. Many Member States do not have a good oversight of FCM businesses so they do not necessarily know where to go to in order to carry out controls, especially regarding importers and suppliers. Limited knowledge of business operators also impedes understanding of the use of new types of material on the market, such as stone, straw and leaves. The complexity of Member States control systems has also been identified as a possible hindrance to the efficient distribution of resources and prioritisation of FCM controls.

Whilst carrying out controls, inspectors may be hampered by a lack of check-lists or guidance, which is particularly important if it is accompanied by a lack of expertise and experience. Part of this problem is also derived from the absence of training. Limitations in laboratories, including NRLs also deters control bodies from undertaking physical sampling as they may have neither the equipment nor methods to carry out the required analysis. Poor traceability on controls and record keeping in case of non-compliance also hampers future risk-based planning. Follow-up enforcement measures and/ or sanctions are not imposed systematically throughout Member States.

Moreover, Inspectors struggle to establish compliance with FCM legislation, in particular as regards Article 3 of Regulation (EC) No 1935/2004 in the absence of specific rules. Certain aspects of legislation addressed at EU level, including the risk assessment, risk management and subsequent enforcement of Non-Intentionally Added Substances (NIAS) are difficult even for those with expertise.

Having summarised the key issues, a number of **best practices** and other ideas materialised during the workshop. The application of the Control Aptitude Level (CAL) is helpful as it provides a starting point for Member States to assess their own capabilities and practical implementation of controls on FCMs. The system can help to organise controls in Member States where division of control responsibility is complex and identify gaps and needs for greater expertise and training. It can also help to prioritise types of controls on businesses easier to achieve and verify to some degree a level of health protection for consumers.

A second key instrument for FCM controls, which was identified in some Member States as best practice, is the use of check-lists. This is particularly important where there is a lack of resources and expertise required to understand and apply the relevant legislation in depth. Moreover, this is a logical tool to use in order to apply incrementally higher stages of control of the CAL approach. Such check-lists provide inspectors with tailor-made documents they can base their controls on, depending on the type of control or business operator that they are inspecting, allowing them to prepare the controls in advance.

The collection and access to data on business operators also greatly facilitate controls in some Member States. Such stored information on business operators includes inspection reports, DoCs and supporting documentation, sampling records and non-compliances. This improves greatly the ability to carry out risk based controls together with other pertinent information such as type of FCM, country of origin, history of non-compliance as well as any sanctions carried out. The need to register and keep a list of businesses in the near future was highlighted as a consequence of the discussions on the new OCR Regulation (EU) 2017/625.

As many Member States struggle with the same issues and problems, facilitating discussion of such issues and sharing ideas and practices on how to resolve them are supported by the Member States. At present, the Member States' FCM Expert Working Group and EU-RL/ NRL meetings exist but mainly discuss, respectively, policy issues and analytical methodology. There is currently, therefore, no real platform for the exchange of ideas and best practices on the wide range of enforcement issues identified in this workshop such as guidance for inspectors, sampling, analysis, inspection reports, determination of compliance, follow-up actions and sanctions. It was agreed that such a platform would also help to improve efficiency and consistency of enforcement, including common approach on sanctions although it remains to be determined who could lead on such a project.

Planning of controls, in particular risk-based controls and possible collaboration between Member States is another aspect considered by participants as being important. Information for risk-based planning can be derived from previous results from official controls and inspections although it can be based also from the RASFF and AAC system, new scientific information, information on business'



compliance records together with the origin of the FCM, the volume on the market, the type of material and consumer that may be using it. At present, information is often limited to RASFF and/or AAC but it was noted that recent discussions in the Member States' FCM Expert Working Group had led to the introduction of a Commission Recommendation on FCM controls. This has been welcomed and further collaborative risk based planning can be supported by the new OCR.

## **7 FOLLOW-UP ACTION**

A number of actions that should be considered following the workshop in order to continue the process of aiming to improve inspection and controls of FCMs were identified by participants as follows:

- I. The Commission will aim to host another similar workshop on enforcement to give the opportunity to Member States to report back on the implementation of best practices.
- II. The discussions and findings of the workshop will be fed into the evaluation of FCM legislation. This is important in particular to consider further actions going forwards to improve, in particular, existing legislation in order to facilitate enforcement as well as to be used as a basis for supporting the need for further harmonisation of FCMs at EU level.
- III. The Commission will raise specific issues on the agenda of the FCM Expert Working Group, 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.
- IV. The results of the Commission Recommendation (EU) 2019/794 on a coordinated control plan with a view to establishing the prevalence of certain substances migrating from FCMs will be examined in 2020, with a view to establishing further structured risk-based control plans at the EU level.
- V. Collaborative efforts should be made to initiate an enforcement platform and/or information network, in order to share information and best practices including check-lists, working documents, risk-based control plans, enhance collaboration opportunities to reduce costs and improve efficiency where resources are scarce and FCMs are not a priority.
- VI. Member States should disseminate the findings of the workshop, including this report within each of its control structures and to all Competent Authorities. Ideally this should facilitate discussion between the participants' organisations and those responsible for inspections and raise awareness.
- VII. Effective training on FCMs for inspectors in Member States should be ensured and best practices identified as part of this workshop should be implemented.
- VIII. Member States should seek to maximise the use of existing resources available in the field of food controls to make progress from Level I to II in the CAL approach in order to improve the possibility of detecting non-compliances during FCM official controls.