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EXECUTIVE SUMMARY OF THE EVALUATION

of the

legislation on Food Contact Materials - Regulation (EC) No 1935/2004

{SEC(2022) 251 final} - {SWD(2022) 163 final}

EVALUATION CONTEXT

Food contact materials (FCMs) include food packaging, kitchenware and tableware as well as items used in professional food manufacturing, preparation, storage and distribution. Basic EU rules on safety as regards their chemical composition and transfer into food have been in place since 1976, with more specific EU rules being progressively added during the 1980s and 1990s, most notably for plastic FCMs. Practical experience and exchanges with stakeholders over the years have raised several fundamental issues with the existing approach to regulating FCMs at EU level. This exercise formally evaluated the EU FCM Regulation (EC) No 1935/2004 (the 'FCM Regulation'), including the approaches taken by the specific measures and the extent to which it has achieved its primary objectives of ensuring a high level of protection of human health and functioning of the EU market.

The evidence to support the evaluation comes from Commission internal studies, an external supporting study and targeted public consultations. Available data was limited as no monitoring framework exists for the legislation and this, together with a lack of data from stakeholders, means that the analysis carried out is subject to limitations. Therefore, some areas are supported by more robust evidence than others.

KEY FINDINGS

The evaluation shows that the FCM Regulation and its implementation are broadly effective in terms of the scope, definitions and traceability rules to achieve the set objectives, with some issues identified concerning effectiveness of labelling and communication to consumers. The general horizontal requirements of the FCM Regulation and in particular those concerning Good Manufacturing Practice (GMP) have promoted specific guidance from industry as well as Member States.

The evaluation concludes that the existing approach and specific rules for plastic FCMs largely ensure the safety of starting substances used in their manufacture, based on a transparent EU risk assessment and authorisation process. The current legislation provides legal certainty for industry with supplementary guidance that is beneficial to stakeholders. Businesses are generally clear on their roles and responsibilities. Member States not only rely on specific rules to carry out official controls, but have also adopted similar approaches for regulating other materials at national level.

However, the EU rules for plastic FCMs are technically complex and resource intensive; for the Commission to manage, for EFSA to provide scientific risk assessment, for EU Member States to implement and enforce and for industry, in particular SMEs, to ensure compliance. Furthermore, the evaluation has identified potential weaknesses in the current approach to regulating plastic FCMs. These concern identification and measures to control non-intentionally added substances (NIAS), to ensure risk assessment and risk management is up to date, deficiencies in the exchange and availability of compliance documentation in the supply chain as well as the scope of the mandatory risk assessment, which does not sufficiently address vulnerable populations or potential exposure to combinations of substances. Collectively, these issues highlight a need to better ensure the safety of the final FCM article brought into contact with food consumed by all EU citizens.

In contrast to the specific complexities of the plastics Regulation, on its own, Article 3 of the FCM Regulation does not define the level of safety or quality expected for FCMs. Further, it does not state how safety should be achieved nor how it can be demonstrated. Many Member States have therefore introduced national measures for non-plastic FCMs. However, those measures often differ, which has created confusion over required levels of safety and legal uncertainty for businesses, particularly SMEs, who may be faced, for example, with multiple testing regimes, increased costs and reduced access to the EU market. The application of the mutual recognition principle has so far not improved this situation.

Member States are able to carry out inspections and controls only in a very limited capacity and the current systems of official controls as implemented cannot adequately enforce the requirements of the legislation. Inspections and official controls are hampered by the lack of specific EU requirements on which to base controls, lack of resources and prioritisation of FCMs compared to other food safety issues, lack of validated methodology to test FCMs and difficulties in identifying FCM businesses. On the other hand, the specific EU rules on plastic FCMs are complex and require a high-level of expertise, which is rarely available in Member States.

The evaluation indicates that the efficiency of the FCM legislation and its enforcement are not fully satisfactory, and subsequent benefits to consumers are still below their potential. Nevertheless, health benefits are expected to exceed the costs. A qualitative analysis suggests that specific EU restrictions for certain substances have led to significant health benefits that may run into hundreds of millions of euros from the time the original intervention was made until the present. Risk assessments that make better use of all available information on substances and extend beyond only plastic could lead to efficiency gains.

Cost savings to industry and EU Member States derive mostly from EU measures on plastic FCMs while evidence is lacking for other material types. Similarly, trade data does not provide clear evidence of enhanced intra-EU trade due to the adoption of the FCM Regulation. Overall, costs to industry are estimated to be around 3% (EUR 3 billion) of the total turnover, composed of administrative costs (~1%) and compliance costs (~2%), including applications for EU authorisation of substances, although these are considered prohibitive for SMEs. Costs for non-plastic sectors however vary significantly, with certain sectors, including paper and board, facing higher costs. The likely cause of this is multiple risk assessment and testing requirements due to the lack of specific rules, although the relevance of other factors – including lost market opportunities – could not be sufficiently quantified.

Rules on FCMs remain very relevant with citizens, who show an increased interest in food safety and related health issues. Businesses continue to need a consistent and predictable regulatory platform on which to produce and trade their products across the EU with minimal burden. However, the current legislation has not fully met the needs and expectations of businesses in this respect, in particular those producing many non-plastic FCMs and to some extent those producing final FCMs, particularly from multiple materials.

Existing rules leave some room for new and evolving science, in particular establishing a clear supportive role of the EU Reference Laboratory (EURL-FCM) in the implementation of the legislation and development of analytical methodology for tests and analyses. Similarly,

the European Food Safety Authority (EFSA) has also worked on identifying emerging risks and set up a network to enhance collaboration among national risk assessors.

However, the evaluation concluded that the approach to regulating plastic FCMs, which is currently geared towards risk assessment and risk management of well-established polymer chemistry, is insufficient to address new and potentially more innovative FCMs. This is highlighted by challenges faced in the implementation of EU legislation on active and intelligent FCMs (AIM). Ongoing changes in the design of materials and their composition including bio-based and biodegradable materials present increasing challenges within the constraints of the current approach. Other novel developments, such as those that incorporate nano-technology and chemical recycling, are presently insufficiently addressed, whereas future needs that cannot be met by current rules are linked to growing consumer interests in re-use, recycling and environmental concerns.

The evaluation indicates that the FCM Regulation is, in general, internally coherent with the main exception of Article 6, which has allowed EU Member States to introduce or maintain national measures in the absence of specific EU rules. Often, those rules differ from one Member State to another and have created a regulatory environment that is not fully aligned with the objectives of the legislation. For specific rules, there is a large gap between what is required to verify compliance (i.e. with specific EU rules on plastic FCMs, including hundreds of authorised substances with specific migration limits for each of them), and what is enforceable in practice with available resources, also considering a significant lack of validated analytical methodology.

The evaluation finds that the FCM Regulation is coherent with other EU legislation concerning food safety and official controls. It is also complementary to other legislation on chemical safety of substances, including the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation, which does not consider specific risks from FCMs. However, unlike FCM legislation, the REACH Regulation as well as sector specific legislation managing the risks from chemicals in consumer products such as cosmetics, places greater emphasis on the hazardous properties of a substance and this in turn is better reflected in those legislative processes.

Gaps may also sometimes exist with the REACH Regulation, as authorisation of substances under the FCM Regulation cannot currently take into account restrictions due to environmental concerns, introduced under the REACH Regulation or the Persistent organic pollutants (POP) Regulation. Apart from the system in the US, regulation of FCMs in the EU is relatively coherent with that in third countries, which in general have followed a similar approach to that of the EU.

There is considerable EU added-value from regulation of FCMs at EU level compared with national level. In particular, the EU specific rules for plastic FCMs have positive effects on effectiveness and efficiency. They provide equal protection of health for consumers across the EU as well as a level playing field for trade, where supply chains are set up to function across the EU, rather than being country specific. Conversely, non-plastic sectors struggle with general, horizontal EU requirements and multiple and often differing national requirements, which have created uncertainty and barriers to trade.

Overall, the FCM Regulation functions, to a certain extent, as expected and partly fulfils its objectives, in particular for plastic FCMs for which specific EU rules apply. The main deficiencies relate to lack of specific rules for FCMs besides plastic, the inability to demonstrate compliance, unavailability of information in the supply chain, challenges in enforcement and lack of prioritisation of the most hazardous substances. The current system in general provides inadequate support to SMEs. Finally, the current legislation and approaches are also largely incompatible with current trends in the switch from materials synthesised from traditional chemistry such as polymers to more novel or natural, sustainable alternatives.