Study supporting the impact assessment on the revision of EU legislation on food contact materials

Executive Summary

Written by EY Consulting
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CONTACT INFORMATION

EUROPEAN COMMISSION
Directorate General For Health and Food Safety
Unit …

Contact: …
E-mail: …

European Commission
B-1049 Brussel

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ABSTRACT

This study compares three Policy Options to support the establishment of an IT infrastructure for information exchange and verification of compliance in Food Contact Materials (FCM). Policy Option 1 proposes a centralized EU IT system, Policy Option 2 (2a and 2b) proposes decentralized national IT systems, Policy Option 3 suggests decentralized industry-managed IT systems. The assessment of such options shows that Policy Option 1 demonstrates strengths in cost efficiency and data management, while Options 2 and 3 show complexities and potential inequalities. Decision-makers can use this analysis to select an efficient FCM IT system. The study contributes insights for establishing an effective, compliant IT system for FCMs.

Executive summary

Context

Ensuring the safety of Food Contact Materials (FCMs) is crucial due to their direct contact with food during production, processing, storage, preparation, and serving. The EU has a detailed legislative framework governing FCM safety, with the Regulation (EC) No 1935/2004 as its main piece of legislation. However, effective information exchange throughout the FCM supply chain is important to maintain safety and compliance. Variances in the completeness and consistency of Declarations of Compliance (DoCs) can lead to gaps in information transmission.

An evaluation of EU FCM legislation highlighted challenges such as limited availability and adequacy of DoCs and supporting documentation, traceability issues, and shortcoming in Member State performance. In response to these findings, an impact assessment was launched, aiming to revise EU FCM legislation to enhance accountability, improve information flow, and streamline compliance efforts.

The focus of this support study is on developing and assessing three policy options that support the establishment of IT infrastructures for information exchange and compliance verification. The development of these IT infrastructure options could provide benefits by increasing information exchange, transparency and ensuring the safety of FCMs throughout the production chain.

Methodology

The methodological approach for this study was strategically designed to address the guiding study questions delineated in the Tender Specifications. Various methodological tools were leveraged to thoroughly collect and interpret data to shape our answers and conclusions effectively. The approach involved three critical phases, namely: Developing Policy Options, Assessing Impacts, and Identifying Implementation Pathways.

The initial phase focused on creating policy options which could rectify existing issues related to FCM supply chains' information exchange and compliance verification. Two primary system options were developed - a centralized IT infrastructure (Policy Option 1) and a decentralized one (Policy Option 2-3). Each system showcases unique organizational governance scenarios which subsequently vary their roles and responsibilities. The approach involved setting the strategy and vision, ascertaining the target state architecture, foreseeing change management, refining functional capabilities, and establishing multi-phase planning. The strategy was guided by the European Commission's objective to facilitate seamless information exchange, boost compliance, and reinforce enforcement.

The second phase involved a qualitative analysis to assess the potential impact of the identified policy options. Where sufficient data allowed, some quantification of the impacts was also carried out. Effectiveness was the central assessment criterion closely aligned with the Better Regulation Guidelines. This assessment considered how well adopting the policy options would achieve the policy objectives set forth in the FCM legislation amendment. Impacts were analysed focusing on the technical impacts associated with the IT systems related to the options. Lastly, a comparative analysis was conducted to highlight the strengths and weaknesses of each approach.

The third phase of the study revolved around identifying the blueprint for implementing and developing the proposed options. Given the lack of a pre-existing FCM specific IT infrastructure, this phase is critical. Different factors were taken into

account, such as systems needed, required investments, involved actors, preconditions, and estimated timelines.

The study employed various methodological tools to inform the three-study phases, including desk research, Open Public Consultation (OPC), survey questionnaires to industry stakeholders, written questionnaires to NCAs and NRLs, a two-part targeted interviews process, and case studies mapping current information exchange process and the existing IT systems. Providing a comprehensive coverage among FCM stakeholders and acquiring the required evidence to develop and assess the potential impact of the three policy options.

Policy Options to support an IT infrastructure for information exchange and verification of compliance

The study outlines three potential policy options conceived to support an IT infrastructure for information exchange and verification of compliance. These options, developed at the request of the European Commission, include:

- Centralized IT system with an EU body principally responsible for management and decision-making (Policy Option 1): An EU body operates and manages the infrastructure in this model. It collects and stores data centrally, exercising control over aspects of the system. The EU body can make decisions faster and more consistently while also maintaining a more secure system. However, this may lead to a dependency on the EU administrative body and can also limit the local adjustments of Member States to their specific needs.

- Decentralized IT system where Member States are principally responsible for local management and decision-making (Policy Option 2): The responsibility is handed over to Member States who set up and manage their IT systems. There are two main sub-options:

  - Sub-Option 2a. EU-level datahub where each Member State uploads its information to an EU-managed platform. This format ensures that data can be transferred and shared between Member States.
  - Sub-Option 2b. Interoperable Member States-managed systems where data stays within national borders. Member States communicate with each other to aggregate data and collaborate. Both sub-options aim to ensure data flow but differ in data aggregation and access. This decentralization may arouse interoperability issues, making data transfer less efficient.

- Decentralized IT system where businesses are principally responsible for management and decision making (Policy Option 3): The management and governance of the system are handed over to businesses. This option may foster innovation by allowing businesses to develop their systems to meet their specific needs. However, it could also lead to dispersed systems that lack standardization, thus placing a heavy burden on businesses to ensure compliance.

To maintain the system in each policy option, administrators are required to manage data flow, conduct routine system maintenance and oversee data integrity. National Competent Authorities (NCAs) are responsible for assessing and reporting the compliance of actors within the supply chain, specifically in verifying the information credibility in the system.

Assessment of impacts of options

The study provides an assessment of the impact of three policy options devised for IT infrastructure for information exchange and FCM compliance verification. Effectiveness was used as the first assessment criterion in line with the Better Regulation Guidelines. Specific Objective 1 is to ensure easy access to information and Specific Objective 2 is focused on easy verification and enforcement.

In terms of effectiveness to reach the aforementioned specific objectives, the following was assessed:

- Policy Option 1 (Centralized EU Database) was found to be highly effective for both objectives. It provides a single database ensuring streamlined access to information, harmonization across the EU, and a simplified process for regulatory enforcement.
- Policy Option 2 (Decentralized National Databases) was less effective due to potential interoperability issues between national databases and the associated costs for Member States. Furthermore, disparities related to funding and implementation across Member States might hinder equal access and verification of FCM information.
- Policy Option 3 (Decentralized industry-managed databases) was deemed the least effective. Its success heavily depends on industry collaboration, which may not ensure comprehensive compliance data and could inhibit easy access for enforcement authorities.

The assessment of other impacts resulted in the following:

- Policy Option 1: benefits include low coordination efforts, cost efficiency due to the use of a single data platform, highly efficient data consolidation, and simple data management. However, it may introduce challenges with customization and local adaptability.
- Policy Option 2a: This model requires moderate coordination efforts, is moderately cost-efficient, and provides moderately efficient data consolidation. Data management could be complex, and governance may be challenging due to the shared responsibilities.
- Policy Option 2b: Like 2a allows each Member State to manage its own data platform, however, these platforms are connected through interoperability. This option may require more coordination effort for optimal functioning and is not cost-efficient due to the complexities of maintaining interoperability. Data consolidation can be complex due to differences in data standards and structures used in different platforms.
- Policy Option 3: This model requires high coordination and could lead to significant variations in systems. Despite a moderate level of cost-efficiency, it's likely to introduce challenges related to inconsistent data consolidation and complex data management, given the variations in standards across industries. The decentralized governance model could make decision-making difficult due to conflicts.
- Each option presents different advantages and disadvantages in terms of implementation and run phase, including coordination efforts, cost efficiency, data consolidation and management, governance complexity, handling inequalities, global and local adaptability, scalability, service delivery, resilience, data protection, and innovation.

The implementation costs of the proposed systems will vary based on the policy option chosen due to data volume. Policy Option 1 stores all FCM data on a single platform, processing a significant amount of data with no duplication. Policy options 2A and 2B store data on Member State-specific platforms, reducing individual platform data volumes. However, 2A duplicates this data in a data-hub which processes a significant data volume. Policy Option 3 stores data on Industry-specific platforms, potentially increasing data duplication for suppliers serving multiple industries.

Due to the lack of existing, comparable IT systems for Food Contact Materials, providing an accurate quantitative cost assessment is a challenge. Furthermore, similar existing systems in other industries and covering other scopes widely differ in scale and scope from the proposed FCM IT System, making their cost data potentially misleading.

Based on this study, potential costs of each policy option could be predicted on three aspects: global cost (overall system cost), local cost (per Member State/Industry), and coordination cost (aggregation and harmonization of data). However, there will be variations in costs depending on the chosen policy option.

Implementation pathways

The proposed implementation for a new IT system for Food Contact Materials (FCM) focuses on the use of an online platform with data entry and withdrawal. The platform is favored for its simplicity of implementation, and use, the availability of the software, competent resources in the market, and a large scale applicability. The system would be accessible to all users via a secure authorization and authentication process with specified permissions managed by system administrators.

Data management will be included in the system, with standardized data formats and templates to ensure consistency and compatibility. The system is expected to be interoperable with existing relevant IT systems where possible. Confidentiality and security measures will be implemented to protect the data.

The implementation of the system is subdivided into pre-conditions and phases. Pre-conditions include the understanding of challenges and the existing process, selecting the corresponding policy option, adapting the legislation and defining guidelines, initiating the collection of data on substances, ensuring stakeholder engagement, and anticipating resources availability.

The implementation phases are structured into five major steps: discover, design, develop, test, and deploy. Each step involves different actors and outcomes, with the timeline varying depending on factors such as the chosen policy option and resources availability.

The implementation process covers technical aspects, including business and technology architectures, management of business processes and user access. The process is to be led by the relevant project team, with the participation of future users and regulation authorities, depending on the policy option. The timeline could span several weeks to a few months per phase.

Conclusions

In the complex context of Food Contact Materials (FCM), the proposed implementation of an IT system aims to facilitate efficient data exchange among a multitude of stakeholders. This study provided an in-depth analysis of potential policy options, platform architectures, and corresponding business models to guide decision-making in the implementation of such IT system.

The three options analyzed in this study form the basis of discussion at the stakeholder workshop, aiming to foster a collaborative decision-making environment. However, the study stresses that an effective IT system requires clear policy directions and harmonized guidelines. The varying IT scenarios, complex as they may be, all represent potential avenues for the effective regulation and management of FCM. The choice of platform architecture should also consider local adaptability and resilience. While the Centralized EU Database seems the most effective, if local adaptability is a priority, decentralized options should be considered. The proactive involvement of all actors, a harmonized regulatory environment, and adaptability will determine the success of the digital transformation.

Limits of the study

The study presents several limitations. First, there is no existing model for such an IT system, making its development experimental and reliant on theoretical frameworks, posing issues for conceptualization and validation.

Second, comparing this proposed system to existing ones in other industries is problematic since they are industry-specific. The FCM IT system would serve more than 14 industries, requiring it to meet diverse industry-specific needs, making these comparisons less relevant.

Third, data collection from FCM stakeholders has been challenging due to the uncertainty of how a new and harmonized IT system could function and impact. Furthermore, stakeholders found difficult to provide precise cost estimates for such an IT system.

Finally, there were difficulties in quantifying impacts due to the lack of existing data or previous performance metrics. Access to complete financial details for the IT systems under evaluation was also a challenge, and the uniqueness of the envisaged IT systems added uncertainty to the accuracy of estimates and projections. As a result, while the study provides a robust qualitative starting point, precise details, and costs may evolve as the system develops.

Étude soutenant l'évaluation de l'impact de la révision de la législation de l'UE sur les matériaux au contact des aliments

Résumé

RÉSUMÉ

To be developed once the English version is approved.

RÉSUMÉ ANALYTIQUE

To be developed once the English version is approved.

Studie zur Unterstützung der Folgenabschätzung bei der Überarbeitung der EU-Gesetzgebung zu Lebensmittelkontaktmaterialien

Zusammenfassung

ZUSAMMENFASSUNG

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