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

Annex

Written by EY Consulting
For the European Health and Digital Executive Agency (HaDEA)
February 2024

HaDEA

EUROPEAN COMMISSION

European Health and Digital Executive Agency (HaDEA)
Unit A2: EU4Health/SMP Food

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LEGAL NOTICE

PDF ISBN: doi: EW:

Manuscript completed in … month / year

Luxembourg: Publications Office of the European Union, 202x

How to cite this report: […]

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1 Study questions

1.1. IT infrastructure required for information exchange – Design

1.1.1 Q1. What are the main elements of a fully functional FCM system for information exchange and how do they work together?

When it comes to creating a new IT system, the interviews with industries showed that they have the 3 following objectives in common: (i) the need for a system that is as easy to use and implement as possible, (ii) the need for the highest level of confidentiality and (iii) the need for efficiency.

The main elements of a fully functional IT system for FCM include both the technological framework and the organizational structure. From a technical and technological point of view, the IT system must contain the following main structural elements:

- System's components:
    - Hardware represents the physical components that hosts the IT system. The FCM IT system can be hosted either in owned servers or in the cloud. This can be decided considering preferences for such system, existing structures, and costs, all while respecting European data privacy regulations.
    - The software components enable the management and processing of data. It also must support custom applications that can be designed for specific FCM information exchange purposes.
    - The system's protocols must be defined since information exchange will need standardized rules for data transmission and communication. For FCMs, the protocols can be defined by country and/or industry.
- Data input and structure:
    - The system should allow authorized users to input or upload information into the system. This includes manual data entry by the supply chain actors, file uploads of DoCs and supporting documents, or automatic data feeds from other existing systems used by the companies or authorities. However, the system should specify data structure which will make it exploitable and harmonized.
    - Processed information should be stored securely in a database, or a file storage system based on its type and requirements. Proper data structuring and indexing ensure efficient retrieval when needed.
    - For the system to interact with other existing IT systems, it should support interoperability standards to ensure seamless data exchange. Actors within the FCM supply chain most certainly have internal IT systems that already contain data and files regarding their FCM-related products. They should be able to feed, via APIs for example, the FCM system without having to re-enter the data manually. Authorities may also have systems that can be connected to the FCM IT system.
- Security and access:
    - Protecting sensitive information and ensuring the privacy and integrity of data is crucial. IT systems implement various security measures, including firewalls, encryption, access controls, authentication mechanisms, etc.
    - To control access to information, the system can rely on authentication mechanisms to verify users' identities and authorization rules to determine what level of access each user will have. This means that depending on the registration profile, the user won't have access to the same access or rights in the system. It is based on permissions given by the system's administrator when the user's account is created. Thus, national authorities can have full access to the data, while FCM supply chain actors will only access DoCs, and supporting information if requested, of the substances and products they operate on. This will ensure both transparency and respect of competition policies.
    - IT systems need to be monitored to ensure smooth operation and to detect any potential issues or security breaches. It is also important to be able to trace activities and events for troubleshooting, auditing, and security analysis.

- User experience:

To facilitate information exchange, user-friendly interfaces are essential. The interface represents what the system's users will see and interact with, like a web portal for instance. The interface should therefore be intuitive for the actors to use. This ties in with what we learned during the interviews with different stakeholders. Whether they were national authorities or FCM supply chain actors, they mainly expressed that one of the most important elements for the system to be accepted and used proficiently is for it to be user friendly. This is especially the case of SMEs that may not have specialized staff to use an IT system, as expressed during an interview with SMEunited.

- From an organizational point of view, many key points should be addressed:
    - Governance of the system must be defined and clear for all actors.
    - Management and decision making should be determined and respected. The Policy Options should be studied to have the best suited system.
    - Regulations should also be adapted in the system to encourage its use and define its rules.
    - Communication around the system and its functionalities should be established. It can be via user guides, e-learnings, keynotes, etc. and can be done by the EC, member states, notified bodies or even industry representatives.
    - Support is also very crucial to help users manipulate the system correctly and provide them with assistance when needed.

1.1.2 Q2. Which systems with a similar functionality already exist and can serve as a model or can be integrated?

Similar systems have been implemented in the EU for different needs but could serve as model for different functionalities:

	IMDS *International Material Data System*	**EMVS** *European Medicines Verification System*	**REACH-IT**	**TRACES NT** *Trade Control and Expert System New Technology*	**Digital Product Passport**
Industry	Automotive	Pharmaceuticals	Chemicals	Agricultural and food industries	Physical goods (all industries affected) traded on the EU market
Area	Global	European Union (EU)	European Union (EU) and the European Economic Area (EEA)	**EU member states** and involves interactions with competent authorities of non-EU countries playing part in the sector.	European Union (EU)
Aim	IMDS is a global data repository that contains information on materials used by the automotive industry. Several leading auto manufacturers use the IMDS to maintain data for various reporting requirements.	EMVS aims to prevent counterfeit medicines from entering the legal supply chain. It was established to enhance patient safety and protect the integrity of pharmaceutical products. Implemented in 2019, it aims to improve the identification and authentication of medicinal products by implementing a standardized verification process	REACH–IT establishes procedures for the collection and evaluation of information on the properties and hazards of chemical substances.	TRACES NT controls the movement of live animals, animal products and plants within the European Union. It facilitates the monitoring and traceability of trade to ensure product safety and compliance with regulations.	The ESPR impact assessment identified that sustainability efforts were hindered by insufficient cross-value chain information access. The Digital Product Passport (DPP) aims enable substance tracing and information access for stakeholders. The goal is to implement sustainability requirements for goods in the EU market, fostering greener products, and reducing costs

		across EU member states.			associated with sustainable investments and compliance.
Regulation	IMDS highlights hazardous and controlled substances by comparing entered data with regulatory-originated lists of prohibited substances (GADSL, REACH, ELV, etc.).	Falsified Medicines Directive (FMD), adopted in 2011.	REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals), 2006.	Official Controls Regulation, 2019. IMSOC Regulation - Implementing Regulation, 2019.	Digital Europe program & Eco-design for Sustainable Products Regulation (ESPR)
Body	Consortium of automotive manufacturers and industry associations.	European Medicines Verification Organization and National Medicine Verification Organizations	ECHA (European CHemicals Agency)	DG SANTE - European Commission	European Health and Digital Executive Agency
Structure	The IMDS serves as a platform for automotive manufacturers and their suppliers to **report and document the composition and properties of the materials and components used in vehicles**. It enables the sharing of data on substances present in automotive parts, including information on their chemical composition, weight, recyclability, and disposal requirements.	It is composed of a **central information and data router (the European Hub)** managed by EMVO and repositories which serve the territory of one or multiple Member States managed by NMVO. Those repositories will all have to be connected to the EU-Hub.	Companies must register substances and, in doing so, collaborate with other companies that register the same substances. **REACH-IT is the central IT system that supports industry, Member State Competent Authorities and the ECHA in the secure submission, processing and management of data and dossiers.** It also provides a secure communication channel between the three parties. IUCLID is a software application that enables the capture, storage, management and exchange of data on the intrinsic and hazardous properties of chemical substances. ECHA is jointly developing this software with OECD. Under the REACH regulation, information submitted to ECHA must be in IUCLID format. ECHA provides the software free of charge on the IUCLID 6 website.	TRACES is the European Commission's online platform for **sanitary and phytosanitary certification required for the importation of animals, animal products, food and feed of non-animal origin and plants** into the European Union, and the intra-EU trade and EU exports of animals and certain animal products. TRACES uses an EU login which is an ID system that is also used by many European Commission services. Once the user creates their account, they need to pair their ID by choosing their role (competent authorities, business operator). The request is automatically sent to the competent authority in the MS. Once the request is validated, the access is be granted to the system. The users can only see the data that concern their business and economic operations or their area (MS).	The Digital Product Passport (DPP) will operate on a decentralized model, with each manufacturing company uploading product information to their own database, which will then feed into the DPP. The European Commission will set data standards, and every company is accountable for providing a DPP for all products and their individual parts. Notably, the DPP will include a central registry for custom and market surveillance authorities. Integrating a universally scannable identifier (like barcodes, QR codes, or RFID tags), the DPP will offer data such as durability, reparability, recycled content, and availability of spare parts. To ensure smooth operation and scalability, common repositories will need setup for traceability data sharing, linking supply chain events, and unique IDs for various goods. This comprehensive arrangement aims to establish a more holistic and standardized

					approach towards product information in the EU market.
Management & Decision making	The IMDS is managed and operated by a consortium of automotive manufacturers and industry associations. **The management and decision-making responsibilities for the IMDS are collectively held by the members of this consortium.**	**EMVO is responsible for managing and making decisions** related to the European Medicines Verification System. It is a collaborative effort involving pharmaceutical industry stakeholders and works closely with NMVOs and regulatory authorities to ensure the effective functioning of the system.	The three parties each have access to specific functions of REACH-IT that they can use to fulfill their obligations under REACH and CLP. **ECHA is responsible for managing and making decisions** regarding the REACH-IT system, ensuring its functionality and compliance with the REACH regulation while Member states authorities are responsible for enforcement.	The **European Commission, through DG SANTE, is primarily responsible for managing and making decisions** related to the TRACES NT system, while considering input from stakeholders and collaborating with EU member states. National authorities designated by EU Member State are responsible for enforcement.	The DPP, centrally controlled by a European authority, will operate per product group with delegated acts determining eco-design and information requirements recorded in the DPP. This centralization ensures uniformity and regulatory compliance across sectors like textiles and home appliances.
Advantages	IMDS helps automotive manufacturers and suppliers comply with various regulations. It promotes transparency within the supply chain by sharing information about parts and substances. It also allows standardization of the data exchanged.	EMVS ensures patient safety by preventing counterfeit medicines from entering the legal supply chain. It also enables the traceability of the medicines which can be useful in case of a recall or investigation.	The system ensures information exchange which promotes transparency and human and environment protection. The safety data sheet is a standard document which makes it easier for every actor to know which information is required in their application. Information also goes up the supply chain in order to share with the suppliers the use maps of the products.	TRACES ensures consumer safety and animal welfare by encouraging transparency and information exchange when it comes to animal trade. It also enhances traceability which makes it easier to track the origin of animal products and monitor animal movements.	The Digital Product Passport (DPP) will enhance consumers' and businesses' product understanding, boost regulatory compliance, and enable better supply chain visibility for public authorities. Through traceability measures, interoperable systems, and common standards, the DPP ensures secure data sharing and facilitates efficient data collection and reporting across diverse stakeholders and IT systems.
Disadvantages	Some suppliers are SMEs and may not afford accessing and using the system. There are costs in order to have access to the system and trainings to use it. Some manufacturers don't exclusively operate within the automotive supply chain; therefore, it may be a burden to manage yet another system.	The system currently only includes prescription medicines. Non-prescription medicines are largely not in scope, with a few exceptions. There is an onboarding fee for the Marketing Authorization Holder (MAH) in addition to a recurring fee that have to be paid. This may be a drawback especially for small actors.	The regulatory process may be slow while facing potentially hazardous substances. IUCLID has some issues with confidential information. Consultations are currently ongoing to address this matter.	SMEs and businesses in less technologically advanced areas may have a hard time accessing or using the system.	This solution is currently in development, with the actual system architecture to be decided over 2024, thus any assessment/comparison with this system might be less relevant than already tested solutions and yield no real-world insight.

1.1.3 Q3. How should the system work to ensure that compliance information is effectively and efficiently captured and communicated to relevant actors including the FCM production chain, food businesses and competent authorities for official control purposes?

There are many possibilities for the system to function and meet the needs of its users, FCM supply chain actors and competent authorities, regarding compliance and information exchange. Many technologies can be relevant following the chosen Policy Option and IT architecture. What it is important to note is that the system must mainly contain:

- An authentication process and authorizations based on profiles following the user's role
- A data architecture defining rules on data integration and storage
- Defined processes for the exchange of DoCs and supporting information, respecting both confidentiality and transparency

Many technologies were considered throughout this study in order to meet the needs of FCM stakeholders. In addition to the online platform that is detailed in the report, other technologies, such as blockchain and P2P, were studied (cf. Annex 2)

1.1.4 Q4. How should information be stored, accessed and transferred and how can the system manage and secure sensitive data? How can it implement a need-to-know approach between the actors that can access the data?

According to responses to the online questionnaire, most industry representatives that answered the survey (56 out of 83 respondents) claimed that storage of safety and compliance information is mainly done in-house on internal digital platforms, whereas a minority of respondents uses a mix of digital and paper means for storage of information (24 out of 83 respondents) or only paper (3 out of 83 respondents). As for the data architecture of the system, it is detailed in Annex 2.

1.2. Information requirements - Design

1.2.1. Q5. What information is required to verify compliance activities and to ensure and demonstrate the safety of all FCM articles including aspects relating to substances, in particular tier 3 substances?

When verifying compliance activities, NCAs normally demand DoCs and supporting documentation proving the safety of the FCM product or material, notably for harmonized materials.

In our industry case studies, we learned that metal packaging industry members (non-harmonized industry) are free to provide their customers with whatever compliance documentation and supporting documentation they believe is appropriate within the confines of EU and EU member state legislative requirements. The degree of complexity and the amount of information provided may vary from the simplest DoC through to detailed documents containing additional confidential supporting documentation under a specific non-disclosure agreement (NDA). The level of information supplied to a particular customer will be dependent on the customers' requirements, expertise, and the nature of any NDA. All DoC would contain a statement of compliance, a list of relevant legislation and any limitations on compliance such as food types, process conditions and Surface area to Volume (fill weight) ratios.

With regards to supporting documentation, this would be any documentation that supports the Declaration of Compliance and will vary between products and applications. In most cases these documents contain confidential and commercially sensitive information so are not generally shared with customers but are made available to control authorities on demand. In some cases, where commercial relationships require it, parts of the supporting documentation may be shared with customers in a controlled way backed up with non-disclosure agreements (NDA). This would be a decision by individual business operators. Supporting Documentation would typically include:

- Upstream DoC, SDS (safety data sheets), TDS (technical data sheets), product test data, etc for the materials used to make the final article (Metals, coatings, sealants, gaskets, etc) as well as documentation from our further upstream where deemed important and if available;
- Migration/extraction data;
- Sensory evaluation data;
- Risk assessments for specific substances or groups of substances (particularly for substances not contained in positive lists);
- Data and calculations on which the limitations contained in the DoC are based;

- Information relating to actual use conditions and the detailed applications (e.g., food types, thermal processing conditions, shelf lives, etc.).

For non-harmonized materials, Member States have specific regulation regarding what is needed to demonstrate their compliance. This means that when conducting inspections on-site, different Member States will require to some extent different compliance information. An overview of these requirements in provided below based on the response of NCAs to the written questionnaires:

- **Belgium** requires Declaration of Compliance (DoC), registration with the AFSCA, the traceability system, and Standard Operating Procedures (SOPs) for both harmonized and non-harmonized substances. For the latter, Belgium also relies on specific national legislation for coatings and varnishes, metals and alloys and paper and board in contact with fatty and humid food, as well as on the Council of Europe Resolution in case national legislation does not exist.
- **Germany** requires DoC and supporting documentation, such as test certificates (migration testing or modelling, NIAS analysis, toxicological information of relevant substances, challenge tests), delivery documents, certificates, recipes, product specifications, purity or food grade certificates, product specifications for harmonized substances. For specific non-harmonized substances, Germany requires voluntary DoCs, proof of compliance with the BfR recommendations, test reports, certificates of safety/ conformity, delivery notes or formulations. In fact, Germany applies national rules for certain non-harmonized substances as stated in the German Consumer Goods Ordinance (Bedarfsgegenständeverordnung). This is the case of printing inks/printed food contact materials and articles). BfR-Recommendations are available for several non-harmonized food contact materials like paper and board, silicones. For elements and heavy metals in enamel, the international standard DIN EN ISO 4531:2022-08 is used. For elements in glass and ceramics including the drinking rim the national standard DIN 51032:2017-07 is used. In addition, Council of Europe Resolution CM/Res(2020)9 may be used for metals and alloys.
- **Estonia** requires DoC for plastics and ceramics. Supporting documentation, as laboratory analysis results, may be requested to complement the compliance information. For other non-harmonized materials, Estonia does not have specific national legislation and/or reporting requirements for compliance but it rather generally established that companies should demonstrate that the product is safe.
- **Austria** requires DoC for harmonized materials, as well as supporting documentation (test reports, delivery notes and compositional documents) in the case indicated by the legislation (plastics and ceramics) and where there are doubts about the conformity of the product to the applicable legislation. Austria applies additional national limit values for zinc, antimony and barium in ceramics and enamels. Test reports, delivery notes and compositional documents are requested to verify the compliance of non-harmonized products.
- **Hungary** requires DoC, supporting documents (on a case-by-case basis - laboratory reports, technical data sheet of raw materials or substances), product specification data sheet and a safety data sheet for harmonized products. Hungary does not have national legislation for non-harmonized substances, for which it equally requires a DoC, as well as supporting documentation (laboratory reports, technical data sheet of raw materials or substances, risk analyzes).
- **Bulgaria** requires DoCs for harmonized substance, as well as supporting documentation demonstrating that the product meets the requirements of the legislation. Bulgaria has national legislation for non-harmonized materials (Ordinance No. 3 of June 4, 2007 on the specific requirements for materials and objects other than plastics intended for contact with food). Accordingly, it requires a written declaration by the manufacturer in accordance with the requirements of Regulation 1935/2004, which must contain data that allow easy identification of the material or object to which it refers. This does not apply to materials and articles made from regenerated cellulose film which are clearly intended to come into contact with food by their nature. Upon request, supporting documentation (data on the results of laboratory analyzes, the test conditions, the name and address of the laboratory where the test was performed) may need to be provided to national authorities.
- **Cyprus** requires DoCs and supporting documentation (results of laboratory analysis) for harmonized substances. No compliance documentation is requested for non-harmonized substances nor supporting documentation.
- **Finland** requires DoCs as a minimum to all actors of the supply chain, as well as proof of traceability. For importers or manufacturers of FCM, supporting documents are also required, at least testing reports. Manufacturers should also have the specifications of the starting substances. Food business operators are requested to provide supporting documentation only in the case that the content of DoCs is not sufficient to prove compliance. Finland requires the same compliance documentation for non-harmonized materials.

- **Slovenia** requires DoCs, traceability, labelling, purpose and conditions of use of FCM, Good Manufacturing Practice (GMP) documentation for harmonized substances. On a case-by-case basis, inspectors may request supporting documentation (product specifications or substances, composition data, material formulation, laboratory test analysis results (SML, OML, test conditions), calculations, including modelling, purity criteria for the substances used). For non-harmonized substances, declarations in conformity with Article 3 of Regulation 1935/2004/EC are requested, as well as traceability, labelling, purpose and conditions of use of FCM, Good Manufacturing Practice (GMP) documentation.
- **Greece** requires DoCs and supporting documentation for harmonized substances (test Reports, as well as documents that ensure traceability). Greece has legislation in place for metals and alloys, paper and board and coatings (National Code for Foodstuffs and Beverages). For non-harmonized substances, inspectors generally require documentation on the production process of the material, substances intentionally used and NIAS, test reports and traceability.
- **Lithuania** requires DoCs when it is mandatory and regulated by EU legislation, as well as supporting documentation (results of migration test performed, composition of material, formulation of materials, DoC received from the suppliers, etc.) and documentation on Good Manufacturing Practice (GMP) rules for harmonized substances. For non-harmonized substances, Lithuania requires that business operators provide adequate Information that would prove safety and suitability on contact with food, including results of migration test performed in house, results of migration test performed by a contract laboratory, composition of material, formulation of materials, DoC received from the supplier.
- **Spain** requires DoCs and supporting documentation (tests that guarantee that the overall migration and specific migration meet the legal requirements) for harmonized products. Spain has national legislation on polymeric materials, other than plastic, intended to come into contact with food (i.e., rubber, coatings and varnishes, adhesives) (Royal Decree 847/2011), as well as on materials and articles made of regenerated cellulose film (Royal Decree 1413/1994). The latter decree establishes that the compliance documentation that is requested when undertaking controls for these types of products is the same as in the case of harmonized legislation. For other non-harmonized materials (for instance glass or metal) the criterion is to verify that article 3 of Regulation (EC) Nº 1935/2004 is met. In some cases, inspectors may consider the legislation that applies in other Member States or criteria reflected in guidance or document delivered by business organizations in the field of food contact materials as well as the Council of Europe.
- **Denmark** requires DoCs for both harmonized and non-harmonized materials. Supporting documentation is required both as provided in EU legislation and on a case-by-case basis to complement DoCs. Denmark has established a national ban on PFAS in FCM of paper and board and has a national list of biocides that can be used for surface treatment of plastic FCMs.
- **Malta** requires DoCs and supporting documentation (analysis and specifications) for harmonized substances. Malta does not have any national legislation or requirement concerning the provision of compliance documentation for non-harmonized substances.
- **Poland** requires DoCs and supporting documents (e.g., results of laboratory analysis) for harmonized substances as indicated in the FCM legislation. National legislation on non-harmonized materials does not exist in Poland, therefore only general requirements for the proof of compliance are applicable.
- **France** requires DoCs and supporting documentation (composition sheet, raw material sheet, migration test reports for the various substances subject to restriction) for harmonized substances. France has national legislation in place for caoutchouc, silicone, stainless steel, aluminum. France requires the presence of a DoC for non-harmonized contact materials. This requirement is provided for in Article 6 of Decree No. 2007-766. Supporting documentation for non-harmonized materials may be requested upon inspection, including technical documentation proving compliance with the principle of inertia of Article 3 of Regulation (EC) No 1935/2004, as well as those proving compliance with good manufacturing practices of Regulation 2023/2006.
- In **Italy**, DoCs and supporting documentation are required for harmonized substances. Italy has legislation in place for as plastic, rubber, paper and cardboard, regenerated cellulose, glass and stainless steel. Specific requirements in terms of compliance documentation for non-harmonized materials is contained in the national law (Ministerial Decree 21 March 1973).
- **Norway** requires DoCs and supporting documentation for harmonized materials, as well as for non-harmonized ones.
- **Portugal** requires DoCs and supporting documentation for harmonized materials. The country has no national legislation for non-harmonized materials but follows a similar approach as for plastic materials when it comes to compliance and supporting documentation.

In the online survey, when asked to indicate what information should be required to pass from one business to the next in the production chain to determine the eventual compliance of the FCM article, respondents indicated the following as most critical: (i) restrictions or limitation of the material as regards the food with which it is intended to be brought into contact (n=86 out of 118 respondents), (ii) restrictions or limitation of the material as regards the time and temperature of treatment storage in contact (n=85 out of 118 respondents), (iii) expected migration (n=56 out of 118 respondents), (iv) identification of hazardous properties and/or other toxicological information of the identified substances (n=46 out of 118 respondents). The following information were deemed as less critical to be passed along the supply chain to determine compliance of FCM articles: (i) a statement that substances of a high concern are not present in the product (n=39 out of 118 respondents), identity of substances used to manufacture FCMs (n=36 out of 118 respondents), identify of substances generated adventitiously in the production process (n=33 out of 118 respondents), analytical testing to demonstrate the level of substances that may migrate into food (n=33 out of 118 respondents), identify of substances used in the processing or conversion of FCM (n=25 out of 118 respondents), physical and chemical properties of the identifies substances (n=19 out of 118 respondents), stability and reactivity of the identified substances (n=19 out of 118 respondents), exposure data to the identified substances including from other sources besides FCM (n=18 out 118 respondents), analytical testing to demonstrate the level of substances in the material (n=18 out of 118 respondents).

In conclusion, to verify compliance activities and ensure the safety of all FCM - including aspects relating to substances - a comprehensive set of information is required. These mainly include a declaration of compliance (DoC) verifying that the manufacturer has adhered to all relevant legislation, along with supporting documentation that substantiates the safety claims made in the DoC. The type of supporting documentation can look different across different jurisdictions and can vary in complexity based on industry, requirements of customers, expertise, and various other factors. This documentation includes, in the case of the metal packaging industry, upstream documents such as safety data sheets, technical data sheets, and product test data. These may be more confidential and commercially sensitive documents, such as risk assessments, which are often only shared under a non-disclosure agreement (NDA).

As demonstrated through the exhaustive analysis of different EU Member States' requirements, there is a uniform emphasis on the presentation of a DoC. However, the need for additional supporting documentation varies and is dependent on the harmonization of materials, national legislation, and case-by-case assessments. In addition to these, the industry members have pointed out the importance of information pertaining to limitations or restrictions on the material's contact with food, time and temperature of treatment storage, expected migration of substances, and the identification of hazardous properties or other toxicological information. The priority and means to obtain these data rely heavily on the specific legislation and regulation mandates of each individual Member State. It is therefore vital for manufacturers to understand and adhere accurately to these national requirements to ensure and demonstrate compliance, and ultimately ensure the safety of all FCM.

1.2.2. Q6. How can existing data be integrated with the new FCM system and how can it be obtained?

An entire project on data relating to the FCM supply chain is to be set up in advance. This will involve not only interoperability with existing systems, which it would be interesting to have (in particular, substances listed in REACH/CLP), but also data formalized by member states (for verification purposes) and industry associations. During our interviews, we found that several industries, like the paper sector, had formulated guidelines for their actors. Although most industries do not have harmonized regulations, some have been able to disseminate "best practices". The work that has been carried out needs to be captured in collaboration with the industries and member states, to establish the best possible vision for each state and each industry.

There are two possible operating modes:

- A direct connection between two applications via APIs
- Between two databases hosted by the European Commission via web services

For fixed data, it is also possible to define a certain number of tables in which the data (substances, industrial guidelines, etc.) will appear, and to make changes as the databases are enriched during MRO.

1.2.3. Q7. How can the quality of the risk assessments that business operators need to do on tier 3 substances along the FCM production chain be ensured, verified and enforced?

In the absence of clear regulations at European level, it would appear that each manufacturer uses a laboratory to carry out its risk assessment in the best possible way. Tier 3 substances are sometimes very difficult to assess, and each manufacturer treats them independently of the others. In this context, the risk assessment includes the requirement for laboratories to include their analytical procedures. In addition, an

explanatory paragraph could be included for each product that has undergone a risk assessment, explaining the approach that led the manufacturer to carry out these checks. Finally, in order to analyze the application of the law in the future, and to be able to collect the work already undertaken by industries on substances, it may be advisable to retrieve these data in an informational database. This database, exclusively reserved for a European body, could be used to monitor the tests carried out on tier 3 substances, so that studies on these databases could be used to carry out verifications, as well as to support the formulation of future legislation concerning analysis methods.

1.2.4. Q8. What would be the risk assessment burdens to the different actors, cost of tests and dossiers in a tiered system, effects on time to market?

The assessment of costs and risks for all FCM stakeholders will vary depending on the Policy Option chosen to implement the system. The detail of this assessment can be found in section 4.3 of the report (Impact Assessment).

1.3. Roles and responsibilities of the various FCM actors along the FCM production chain - Design

1.3.1. Q9. What are the roles of the different actors in accessing the data?

Currently, business operators at each stage of the supply chain are bound to provide compliance information to the downstream actor for the latter to complete their internal compliance work. Additional information on the use of the material/product may be requested by upstream actors to downstream clients for the former to perform risk assessments. Business operators are responsible to make sure that their FCM products are safe and are bound to have compliance documentation and supporting documentation in-house. NCAs may inspect business operators on-site and require them to provide both compliance and supporting documentation.

According to the responses to the online survey, currently actors in the FCM supply chain exchange both compliance (53 out of 75 respondents) and additional documentation (including supporting documentation) (60 out of 72 respondents) mainly upon request only. Respondents have generally indicated that it is challenging to obtain such documentation upon request, as the latter must be reiterated often (33 out of 75 respondents) or very often (19 out of 75 respondents). Most respondents indicated that emails are the main tool to exchange information with other actors along the supply chain (58 out 75 respondents for compliance documentation and 60 out of 72 respondents for additional information). Less respondents indicated the use of dedicated digital platforms for the exchange of compliance documentation (27 out of 75 respondents) and additional information (18 out of 72 respondents). The exchange of information with National Authorities (NA, NCA, NRL) follows a similar path: both compliance (63 out of 75 respondents) and supporting documentation (51 out of 75 respondents) are exchanged upon request of the National Authority, mainly via email (39 for compliance documentation and 30 for supporting documentation out of 75 respondents).

In the written questionnaires, Member States have detailed the way they access compliance and supporting documentation when carrying out controls. Member States (Belgium, Germany, Estonia, Austria, Finland, Greece, Lithuania, Denmark, France, Italy, Norway, Portugal) indicated that access to compliance and supporting documentation is granted to authorities on the site of the business operators through either a digital or paper-based system. The authority would check the presence of such documentation, which then remains on-site. Accordingly, in case the documentation is not directly available, the operator would subsequently share it with the authorities via email or occasionally in a paper-based format. When conducting samplings for a risk assessment, authorities may request business operators to provide compliance and additional documentation, which is then exchanged either via email, paper-based format or even via telephone call (Germany).

In their position papers submitted in the framework of the OPC, some stakeholders claimed that information on product composition only needs to be made available to relevant specific individual actors in the supply chain (UNESDA Soft Drinks Europe) or even exclusively to national or European authorities (TotalEnergies Corbion, The Alliance for Beverage Cartons and the Environment), whereas others sustained that all actors should have access to such information (Swedish Chemicals Agency), in particular that on the content of hazardous substances in FCM (CHEM Trust), (iii) the need for manufacturers outside of the EU to be instructed on how to comply with European safety requirements and be integrated in any digital tool for information exchange (Eurofins Consumer Product Testing).

In terms of roles and responsibilities of different actors in the FCM supply chain, most contributors to the OPC (n=303, 93%) agreed (n=128) or strongly agreed (n=175) with the need for the FCM legislation to specify to which actors' specific rules of information requirements apply.

The proposed Policy Options establishing IT systems for information exchange and verification of compliance mainly rely on the current distribution of roles and responsibilities in terms of provision and exchange of compliance information across the supply chain and to competent authorities. As established in the industry case studies and the subsequent "use cases" applying the Policy Options to different supply chains, different actors in the supply chain play varying roles in accessing data regarding the compliance of FCM. Suppliers, starting the chain, are responsible for submitting compliance documents, such as Declarations of Compliance (DoCs), into the IT system. These documents can be submitted in different formats based on current legislation. In case of additional information requests from other stakeholders, suppliers have the discretion to share further supporting documentation under a Non-Disclosure Agreement (NDA).

For businesses operating outside of the EU, they typically work through importers or manage branches within a member state to ensure the appropriate DoCs are submitted into the database. Manufacturers are capable of accessing their suppliers' DoCs through the system. They also provide their own DoCs to subsequent users, like food business operators. They supply information about the use of their materials to their suppliers and receive feedback about the utilization of their products from subsequent users. If needed, they can also disseminate additional information and supporting documentation to other actors under NDAs. Regarding regulatory authorities, competent authorities in Member States have unrestricted access to information at all times. They can pull data for inspections as needed, which includes supporting documentation. Along with this, the system could also serve as an official means of communication with supply chain actors for additional requests.

In decentralized IT systems, the oversight lies either with individual Member States, with each maintaining its own system of exchange, or with industry associations that create distinct databases for their own clusters, accordingly. While the method of information exchange remains the same, the specific overseeing authority varies based on the system. Regardless of the arrangement, competent authorities maintain visibility into the database systems to perform compliance checks.

1.3.2. Q10. Who should be responsible for providing information and at what stage of the production chain? Who is the data owner and responsible for keeping data up to date?

In the current system, each actor in the supply chain is responsible for providing the compliance documentation of their product or substance to the next actor. Business operators may go back to previous actors in the supply chain to ask for additional or missing information. The actor, at each step of the supply chain, that gets inspected by NCAs has the burden of providing to the latter the compliance documentation, as well as any supporting and additional documentation proving the compliance and safety of their products. During several interviews (Metal Packaging Europe, CEPE, CEPI, Flexible Packaging Europe, Denmark, Hungary), the Study Team learned that, in the case of confidential information, actors in the supply chain make use of third parties (i.e., external and independent specialized laboratories). The latter are communicated the full confidential information on the product to perform a risk assessment. The report produced by the third party is later communicated to the following actor in the supply chain upon request and signature of NDAs. The report may be provided to NCAs during inspections. NCAs will then check the report and contact the third party to have the full confidential information.

With the introduction of an IT system, the actors will input their data (DoCs and supporting information) in the system. The information will be secured thanks to a validation process and an authorization system allowing only users with an NCA profile to access confidential information without request. The data and documents must be updated by the supply chain actors in case of any change in the composition or usage of their FCM related products. NCAs may also update the system in case of a compliance assessment on the products.

On the basis of the industry case studies and the subsequent "use cases", the responsibility for providing compliance information begins with suppliers. They are required to submit their compliance documents, such as Declarations of Compliance (DoCs), into the IT system. This data ownership extends to additional supporting documentation, which they can choose to share under a Non-Disclosure Agreement (NDA) upon request. Manufacturers sit at the subsequent stage of the production chain and access compliance data from their suppliers. In their turn, they supply their DoCs to the next users, typically food business operators, and potentially provide additional information and documentation under NDAs. For businesses operating outside the European Union, typically represented by importers or branches within a member state, they are required to submit appropriate DoCs into the system, essentially handling their data.

Throughout these processes, each respective actor – suppliers, manufacturers, and businesses operating outside the EU –operates as the data owner for their particular stage of the production chain. They are responsible for keeping this data accurate and up-to-date. Lastly, regulatory authorities – the competent authorities in member states – have unrestricted access to all information at all times, allowing them to verify compliance throughout the entire production chain. They do not own the data but are vital in its oversight and regulation.

1.3.3. Q11. How can the burden of accessing data be minimized for FCM business operators, especially those down the supply chain and responsible for the FCM article?

During interviews, the majority of actors representing FCM manufacturers expressed frustration about the delay in accessing information about the components of their products. This is mainly caused by the fact that every intermediate manufacturer must contact each one of their suppliers to have the information about the components, which is time-consuming. In an IT system, as previously described, all actors (from raw material suppliers to FCM business operators) must input all information and documents regarding each and every one of their FCM related products or substances. This enables actors down the supply chain to access DoCs (and supporting information if requested) of the component immediately and without any delay once they are validated as a client by the manufacturers.

1.3.4. Q12. Should there be a system which helps to ensure the risk assessment process is done correctly prior to playing on market e.g., by means of notified bodies? Should they certify the product or the risk assessment process done by a business operator?

During the interviews, actors representing FCM operators (suppliers and manufacturers) generally did not find it useful to have their products re-verified by notified bodies. The use of a laboratory is almost systematic in their verification process, and double verification would only generate additional costs and delays, with no significant gain in reliability. Finally, it appears that laboratories often prescribe a wide range of tests, even when the product is not concerned, which could give rise to a financial conflict of interest. However, it would be wise to give further thought to the laboratories authorized to issue risk assessments, and to carry out regular audits to ensure that risk assessments are carried out objectively and rigorously.

1.3.5. Q13. How can the system be optimized taking into account the resources of SMEs?

Several strategies can be used by the FCM IT System's administrator(s) to optimize the system according to the financial, human, and technological resources of SMEs, who will be vital end-users of the system and must be smoothly integrated to ensure effective and efficient functioning.

These strategies will vary depending on the chosen Policy Option:

PO1 (centralized governance at the EU level)

1.2 Financial resources: universal access across SMEs can be ensured by introducing a tiered subscription model or nominal access costs, while also guaranteeing necessary funding from EU budgets to prevent undue burdens on smaller entities.

1.3 Human resources: regular training, webinars and workshops for SME personnel can be scheduled to ensure that they are proficient and comfortable in using the system. Online access to user-friendly training materials and dedicated support services can also minimize the need for extensive internal training resources, that would be costly for SMEs.

1.4 Technological resources: design the system to be inherently intuitive and user-friendly, reducing the need for advanced technical competencies. Making it adaptable and scalable to various sizes of businesses, will reduce the need for SMEs to invest in additional infrastructure (for instance, operation on cloud-based platforms can allow easy access and minimal maintenance concerns). Given the potential diversity in IT maturity among SMEs, the system should offer compatibility with a range of software and hardware setups; endorsement of open standards and interoperability would facilitate integration with existing workflow in SMEs, reducing costs and enhancing usability.

PO2A (decentralized governance between National Authorities, with an EU-level data hub)

1.5 Financial resources: resources can be pooled across the EU to fund the prime components of the system, reducing the imposed burden on individual Member States and thereby indirectly on SMEs. Member States could further extend support to SMEs within their jurisdiction through subsidies or incentives for system utilization.

1.6 Human resources: local training initiatives led by Member States can bridge the gap between technology and users, tailored to the specific regional needs and linguistic diversity. It further allows Member States to share best practices and training resources through the centralized hub.

1.7 Technological resources: maintaining a degree of homogeneity across the system despite decentralization will be essential, to ensure seamless data exchange and interoperability and to help SMEs to bypass expensive customization and complex integrations and adapt more easily to the system. Solutions that will reduce infrastructure costs for SMEs and facilitate secure data sharing should be favored. Crucially, the system should offer flexible and user-friendly interfaces to accommodate SMEs

with varying degrees of technological competency. Member States could also provide technical support centers to aid SMEs within their regions.

PO2B (decentralized governance between National Authorities, with interoperability)

1.8 Financial resources: efforts should be made to minimize cost implications to SMEs, which could involve subsidizing system usage, implementing cost-effective technologies, or creating economies of scale wherever possible. Each member state will have domestic control over their data platform, thus they could arrange funding initiatives to support SMEs in adopting the system.

1.9 Human resources: the provision of regular, accessible training and support will be key to ensuring SMEs can effectively utilize the system. Such training can be locally-driven in line with the decentralized structure, attuned to the regional language and industry context, thus making it more relevant and effective

1.10 Technological resources: the system must be designed with user-friendliness and versatility, considering the diversity of SMEs' digital proficiencies. Standardizing data format and exchange protocols will smooth interoperability among national platforms. Solutions that reduce infrastructure costs and ensure ubiquitous accessibility should be implemented. Moreover, the system should offer robust technical support. As resources within SMEs are often stretched, lean IT teams may have difficulty managing implementation and troubleshooting without external help.

PO3 (decentralized governance between Industries)

1.11 Financial resources: industry associations can leverage their collective bargaining power to negotiate cost-effective contracts when commissioning the IT system. This could significantly reduce the financial burden on individual SMEs. Also, industry representatives may have direct channels to funding sources, like sector-specific grants or private investors, which can be utilized to offset system costs.

1.12 Human resources: can be maximized through peer-to-peer learning opportunities provided by industry representative forums or working groups. Cross-industry collaboration will encourage knowledge sharing, can supplement formal training schemes, and provide real case examples. This can be executed cost-effectively through webinars or online workshops, ensuring even remote or smaller SMEs can participate.

1.13 Technological resources: since the system will be governed by industry representatives under this Policy Option, it will ensure that the IT System is designed specifically to meet the unique needs of that industry. Consequently, the technological resources of SMEs may be more effective and sufficient as the burden of data processing and software capabilities requirements can be lessened. Ensuring that the system remains interoperable and adheres to a common standard will facilitate seamless data exchange with other industries and avoids the risk of fragmentation, which would be costly for SMEs to absorb.

1.3.6. Q14. How would the system function for suppliers outside of the EU?

The evaluation of the FCM legislation identified issues with the interaction between non-EU suppliers and EU business operators in the supply chain for what concerns the identification of the former and the provision of compliance information. In the online survey, the issue of the completeness of compliance information provided by non-EU suppliers was investigated. As a result, respondents resulted to be very divided. Slightly more respondents (n=44, 37%) positively rated the quality of compliance information provided by third-country actors (n=36, 30% as satisfactory, n=5, 4% as good, n=3, 3% as very good), compared to those that rated it as poor (n=30, 25%) or very poor (n=9, 8%). Few stakeholders took a position on the integration of non-EU suppliers in a future IT infrastructure for information exchange and verification of compliance.

During interviews, industry representatives tended to agree with a full integration of non-EU suppliers into the IT system. Notably, they pointed out that, as long as non-EU suppliers are bound to the same legislation on FCM and participate in the same market, the same conditions should apply as for EU actors on the IT infrastructure (Silicones Europe, CEFIC, Flexible Packaging Europe, EUPIA). Interviewed NCAs also agreed that the inclusion of non-EU suppliers in the IT infrastructure is needed. They pointed out that this would be central to overcome the issue of the lack of information coming from non-EU suppliers, as well as allowing competent authorities to get access to full compliance information more easily (France, Hungary, Germany, Poland, Austria, Denmark).

Businesses operating outside of the EU need to make sure their compliance data aligns with EU standards. Case studies informed the study team that such actors typically rely on importers or branches of the business within a Member State, which are charged with ensuring the appropriate Declarations of Compliance (DoCs) are provided to supply chain actors.

In the context of an IT-based compliance system proposed in the Policy Options, these actors (importers or branches in Member States) would be required to input their DoCs and, if necessary, additional supporting documentation into the relevant IT database. This could be done through the digital platform, ensuring that the compliance information is available to other actors in the supply chain within the EU.

These actors would retain responsibility as the data owners for their respective stage in the supply chain, so they would need to keep the shared compliance data current and accurate. Access to this information by other actors in the supply chain and regulatory authorities remains unrestricted, ensuring effective scrutiny and compliance checks by competent authorities.

1.4. Roles and responsibilities of the competent authorities of the EU Member States - Design

1.4.1. Q15. What should be the role of competent authorities? Should they verify compliance of actual FCMs or should they rely on notified bodies for that? Should they be assisted by delegated bodies for official control purposes?

Based on the triangulation of the data collected during the various consultation activities, there is a broad consensus among the different stakeholders that national competent authorities should verify compliance of actual FCMs:

- Most of the NCAs which were interviewed and replied to the written questionnaire agreed that NCAs should have the responsibility to carry out verification of compliance and controls of FCMs (Belgium, Germany, Greece, France, Finland, Malta, Poland, France, Norway, Portugal).
- In the OPC, there was equally large agreement on the fact that Member States' competent authorities should carry out regular physical and documentary checks on FCMs (n=239, 73%).
- 48% of industry stakeholders who replied to the online survey agreed to a very large or to a large extent that Member States' competent authorities should carry out regular physical and documentary checks on FCMs.

The analysis of the different data collected for the purpose of the Study reveals mixed views among stakeholders on the involvement of notified bodies or delegated bodies to verify compliance of actual FCMs and on the assistance of delegated bodies for official control purposes.

On the one hand, most industry representatives who replied to the online survey believe that notified bodies should not be used to verify compliance of actual FCMs. 55% of industry stakeholders who replied to the online survey agreed to a very low extent or to a low extent that Notified Bodies should be used for the verification of compliance and would help businesses to ensure safety; and 55% of respondents agreed to a very low extent or to a low extent that Member States competent authorities should be supported by the use of delegated bodies as provided by the EU Regulation 2017/625 for official controls. The position papers of some business associations which were submitted in the framework of the OPC confirm this finding. Notably, some stakeholder disagreed with the involvement of notified and delegated bodies for official controls or the verification of compliance, as this would (i) increase bureaucracy and administrative burden and potentially create bottleneck to putting products on the market (The Alliance for Beverage Cartons and the Environment) and (ii) notified bodies would not be helpful to businesses to reduce costs (EFCEM European Federation of Catering Equipment Manufacturers). However, other business association in the framework of the OPC proposed that the use of notified and delegated bodies is available to Member State authorities on a voluntary basis.

Some Member States' NCAs also argued that verification of compliance should be the sole responsibility of national competent authorities (France, Greece, Malta, Poland and Portugal). To justify their views, they argued the following:

- There is no need to delegate these tasks to notified bodies or delegated bodies and it is not pertinent as national authorities are already carrying out those tasks (Poland, France).
- Competent authorities are impartial and are not exposed to conflict of interest (France).
- The performance of the controls by national authorities would ensure those controls are proportionate and comply with the OCR (Portugal).

Importantly, if NCAs are to carry out verification of compliance without notified bodies or delegated bodies, it appears essential to increase their capacity:

- The French NCAs recommended to increase the capacity of NCAs in the future to carry out control to verify the safety of FCMs.
- The Hungarian NCAs indicated a lack of resources of NCAs to justify the need of support of delegated or notified bodies.

- On the other hand, in their responses to the written questionnaire, some NCAs (Austria, Belgium, Finland, Hungary and Germany) did not exclude the possibility to have Notified Bodies assisting competent authorities in carrying out verification of compliance under specific conditions:

- The Belgian NCAs stated that "the final responsibility must still be taken by the national competent authority", as well as that "it should be ensured that notified bodies do not create an extra step and burden in the control of FCMs" and recommend drawing up strict rules "so that all notified bodies in different member states follow the same rules on enforcement, as well as the rules on monitoring/controlling of these notified bodies".
- The Finnish NCAs argue that there should be a verification of Notified Bodies if they are used to assist competent authorities.
- The Austrian NCAs underline that a combined system of NCA and notified bodies could be conceivable if "operated transparently and with little resource input".
- The Belgian and German NCAs mentioned that the integrity of Notified Bodies should be ensured under this system and that conflict of interest should be avoided by ensuring that Notified Bodies can work independently from the industry.

Moreover, the results of the OPC showed a rather large acceptance of the proposal of involving delegated bodies in the support of Member State authorities. Namely, 41% of respondents (n=133, 41%) tended to either agree (n=88) or strongly agree (n=45) with the use of delegated bodies to support Member States' competent authorities during official controls as provided by Regulation 2017/625. Regarding the use of notified bodies for the verification of compliance and on whether they could be helpful to businesses to ensure safety, responds to the OPC were divided: 39% of the respondents agreed or strongly agreed with this statement and 37 % respondents disagreed or strongly disagreed with this statement.

In the context of the proposed Policy Options, the role of competent authorities should primarily center around verifying actual FCMs' compliance. This responsibility involves maintaining unrestricted access to all compliance data at all times and being at liberty to conduct routine and necessary ad-hoc inspections. Competent authorities are to oversee that all compliance information is accurate and up to date. They are required to verify that all actors in the supply chain, including suppliers and manufacturers, as well as businesses operating outside the EU, provide the appropriate Declarations of Compliance (DoCs) and support documentation. Regardless of whether a centralized or decentralized IT system is used, competent authorities should have visibility into these databases to perform compliance checks. In a decentralized system, competent authorities might also be responsible for managing a national database or overseeing industry-specific databases.

The option of utilizing notified bodies or receiving assistance specifically from delegated bodies is not fully supported by stakeholders however it could be contemplated, potentially on a voluntary basis, provided that it fits within a transparent and efficient framework, avoiding extra burdens and conflicts of interest. Regardless of how the system is structured, it's critical that competent authorities remain at the helm of enforcing FCM compliance.

1.4.2. Q16. What is the level of expertise that the competent authorities should have?

While the competent authorities from EU Member States should have the technical skills necessary to interpret the scientific data from risk assessments of FCMs, the data collected by the Study Team in the written questionnaires and during interviews reveal that national competent authorities in charge of the controls in Austria, Denmark, Estonia, Germany, Malta, Norway, and Portugal tend to lack expertise in chemistry, analytical methods for substances and/or toxicology. A lack of skills in the field of FCMs was also reported by Hungary both at the national and regional levels, and by Austria and Greece at the local level:

- In Austria, food inspectors are supported by the chemists working at the central level.
- In Greece, GCSL inspectors at border posts can request the advice from the central service of GCSL (DAF) which has a sufficient knowledge and expertise in FCMs in order to provide instructions and coordinate Chemical Services dealing with FCMs official control at border posts.

In the case of Denmark, experts from the technical university of Denmark provide specific advice on a case-by-case basis to the officials in charge of FCMs controls. Only in France, the NCA reported to have sufficient expertise on FCMs as competent authorities in charge of FCMs controls are organized in a control network specific to FCMs. Besides, it appears essential that the NCAs have a strong and up-to-date knowledge of the

FCMs regulations. In specific, the NCA from Norway reported a "constant need to update the competence on the FCM regulations", mentioning that non-harmonized materials are particularly challenging to control. On that regard, the Polish NCAs indicated that the inspectors at the local and border levels receive training periodically and in the event of a significant change in provisions concerning food safety including FCM.

In conclusion, competent authorities from EU Member States handling FCMs need significant expertise in interpreting scientific data from FCM risk assessments, including a strong understanding of chemistry, analytical methods for substances, and toxicology. Furthermore, they need to be up-to-date on evolving FCM regulations. The current state reveals a gap in these skill sets in many countries, suggesting the need for continuous education and, potentially, support measures such as assistance from external experts or specific networks targeting FCM controls.

1.4.3. Q17. How would they decide on the compliance of a product? Which information would they have and against which criteria would they verify compliance?

Currently, national competent authorities decide on the compliance of a FCM product based on the compliance documentation that the business operators provide for the product (on-site during inspections or exchanged via email before or after the inspection), notably the presence of such documentation and on its content, as well as on the supporting documentation (e.g., laboratory analysis, migration testing). This mainly applies to harmonized products for which a template DoC exists in the legislation.

The challenge remains for non-harmonized products. During interviews, some Member States have highlighted how the lack of a structure for providing information for the aforementioned products limits the quality and availability of sufficient information when checking compliance (Germany, Poland). For the latter, the lack of harmonized guidance from the EU has led to the spread of a plethora of different legislative approaches when it comes to the verification of compliance of such products. Certain Member States require DoCs equally to harmonized products.

This is the case of countries belonging to the Nordic Council of Ministers (e.g., Denmark, Finland, Norway) that have developed national legislation equalizing the burden of providing compliance documentation for both harmonized and non-harmonized products. For the latter, guidance is provided to business operators, as well as inspectors, through the 'Nordic checklist for food contact materials'1 developed by the Nordic Council of Ministers. The Nordic checklist contains several templates. The different templates provide check points on the minimum requirements for a declaration of compliance for all types of materials. The templates are meant to be used by industry and trade as guidance for drafting a declaration of compliance. Furthermore, the check lists are also meant to be tools for the public food and FCM inspection. Equally, Belgium requires a DoC for all types of FCM (RD 11 May 1992) and applies specific rules coatings and varnishes, metals and alloys and paper and board in contact with fatty and humid food2. When legislation and guidance is not present at the national level for certain products or materials, the country relies on the legislation of other Member States or on the Council of Europe Resolutions (CM/Res(2020)9).

Other countries do not require DoCs for all FCMs but have establish specific requirements concerning the compliance information to be provided in several cases of non-harmonized products. In Germany, in addition to the general EU legislation (Regulation (EC) No 1935/2004, Regulation (EC) No 2023/2006), the German Food and Feed Code (LFGB) and the German Consumer Goods Ordinance (Bedarfsgegenständeverordnung) apply. The German Consumer Goods Ordinance covers amongst other rules for printing inks/printed food contact materials and articles. Apart from the legal provisions, in Germany the Recommendations on Food Contact Materials published by the Federal Institute for Risk Assessment (BfR) are used by competent authorities and industry as a guiding tool3. BfR-Recommendations are available for several non-harmonized food contact materials like paper and board, silicones etc. For elements and heavy metals in enamel the international standard DIN EN ISO 4531:2022-08 is used. For elements in glass and ceramics including the drinking rim the national standard DIN 51032:2017-07 is used. In addition, Council of Europe Resolution CM/Res(2020)9 may be used for metals and alloys.

Austria has established additional limit values for zinc, antimony and barium for ceramics and enamels (National Ceramics Ordinance (BGBl. II No. 259/2006)). Greece has national provisions for metals and alloys (art 22), paper and board (art 24) and coatings (art 28), as included in the National Code for Foodstuffs and Beverages, whereas the provisions for paper and board are under revision. In Spain, the Royal Decree 847/2011 establishes the list of substances that are authorized to manufacture polymeric materials, other than plastic, intended to come into contact with food (i.e., rubber, coatings and varnishes, adhesives, etc…). In addition, Royal Decree 891/2006, related to ceramic materials and articles intended to come into contact

[1] https://www.norden.org/en/publication/nordic-checklist-food-contact-materials

[2] https://www.health.belgium.be/fr/alimentation/securite-alimentaire/materiel-de-conditionnement-et-demballage/materiaux

[3] https://www.bfr.bund.de/en/bfr_recommendations_on_food_contact_materials-308503.html

with food, introduced the requirements indicated in Directive 84/500/CEE and Royal Decree 1413/1994, relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs, introduced the requirements indicated in Directive 2007/42/EC. France established a range of national regulations on a number of materials (rubber, silicone, stainless steel, aluminum, etc.) and certain national technical recommendations4. Italy established national legislation on specific materials, such as plastic, rubber, paper and cardboard, regenerated cellulose, glass and stainless steel (Ministerial Decree 21 March 1973), as well as for aluminum and ceramics (Decree 18 April 2007 n.76 and Decree 4 April 1985 updated with Decree 1 February 2007). In Slovakia, there are national regulations applicable to all types of FCMs at the general level and specifically focused on paper, ceramics, glass, plastics, metals, regenerated cellulose, elastomers and rubber, wood and cork, textile FCMs, surface treatment and printing of FCMs (Regulation 9 June 2003 No 1799/2003-100, which issued the fifth head of the Food Code governing materials and articles intended to come into contact with foodstuffs as amended, and Regulation 6 February 2006 No 06267/2006-SL, which issued the head of the Food Code governing microbiological requirements on foodstuffs and packaging materials on foodstuffs).

During the consultations, the Study Team learned that business organizations representing industries that commercialize non-harmonized products have also developed guidance and checklists to support their members demonstrate compliance of their products. This is the case of the guidance papers developed by FEICA for their members in the adhesives industry, for them to produce compliance documentation, or the several guidance notes produced by EUPIA for customers using printing ink in FCM as well as for members to fill in their 'statements of information'.

In the OPC, stakeholders have strongly supported the following proposals concerning means of demonstrating compliance of FCM products: (i) a mandatory DoC for all FCMs, with 142 respondents strongly agreeing (43%) and 119 agreeing (36%); (ii) full information on the composition of products shall at all times be easily available to competent authorities throughout the supply chain, with 127 respondents strongly agreeing (39%) and 99 agreeing (30%); (iii) DoC based on a fixed format with obligatory fields, with 108 respondents strongly agreeing (33%) and 103 agreeing (31%).

The establishment of an IT system in the future would significantly support National Competent Authorities (NCAs) in accessing compliance information provided by business operators. Currently, NCAs determine compliance based on documentation provided by these operators, which can sometimes be challenging, particularly for non-harmonized products. This situation has created a patchwork of different legislative approaches across Member States.

An IT system would streamline the process by serving as a repository for all required compliance documents, making it easier for NCAs to review and verify product compliance. This would be particularly beneficial given the strong stakeholder support for mandatory DoCs for all FCMs, full transparency on the product composition throughout the supply chain, and standardization of the DoC format with obligatory fields. These enhancements, facilitated by the IT system, would create a more efficient, effective, and transparent regulatory environment for FCMs, helping the NCAs to better manage compliance.

1.4.4. Q18. How can enforcement authorities access all data without delay and burden, at all marketing stages to carry out controls?

In the open public consultation (OPC), most respondents (n=205, 63%) agreed with the proposal of a digital or electronic system to contain and transfer supporting compliance documentation as opposed to a paper-based system. According to the position paper of Verbraucherzentrale Bundesverband e.V., such a system would be beneficial to facilitate the work of competent authorities. Similarly, a majority of respondents to the online survey (n=66, 60%), confirmed that DoCs and documentation supporting compliance should be contained and transferred along the supply chain and to competent authorities in a digital or electronic system.

Several NCAs have identified benefits in setting up a digital or electronic system to transfer information and carry out controls on FCMs. Austria explained that an IT infrastructure would enable the NCA to have compliance documents readily available for being checked, which would speed up the work of inspection. Similarly, Hungary found benefits for both inspections and for the monitoring system, in terms of easier checks of documentary evidence which would not need to be asked for. Germany highlighted that, in the case that all the compliance and supporting information is accessible to competent authorities through an IT infrastructure, this would help to perform verification of compliance and FCM control. Easy access to information would also in turn help industries to access information to be able to perform compliance work.

A future IT system, whether centralized or decentralized, would serve as a repository for all compliance documents, including DoCs, laboratory analyzes, migration testing, and other supporting documentation.

[4] https://www.economie.gouv.fr/dgccrf/Fiche-generale-relative-a-la-reglementation-des-ma

Having access to all of this information would allow authorities to promptly and efficiently review and verify product compliance at any stage in the marketing process. The ease of access to comprehensive, real-time data would greatly enhance the ability of enforcement authorities to monitor compliance and respond swiftly and appropriately to any issues. Moreover, IT systems would standardize the compliance process, reducing the burden of navigating varying compliance requirements across different regions, particularly for non-harmonized products.

1.4.5. Q19. Should there be regular control plans for FCM and what elements might this include, e.g., documentary checks, analytical testing and frequency?

Many EU Member States already have multi-annual national control plans for FCMs as required by the Official Controls Regulation 5, however there is no such regular control plan at the EU level. Based on data collected through interviews and written questionnaires, among the NCAs that have expressed an opinion on this matter, Austria, Germany, Italy, Malta, Poland and Slovakia supported regular control plans. In specific, they provided the following arguments to support the use of formalized control plans: "a formalized control plan could help to ensure the safety of FCMs" (German NCAs), control plans facilitate enforcement (Austrian NCAs), formalized control plans are "necessary for coordinated and effective supervision" (Poland). Only the NCAs from Lithuania did not believe that formalized control plans would facilitate the verification of compliance and ensuring the safety of FCMs.

The NCAs from Austria, Spain and Finland openly supported the definition of coordinated and regular control plans at the EU level. However, the Austrian NCAs underlined that it can be complicated to set up regular controls plans at the EU level with 27 Member States. On the other hand, only Hungary formally rejected the idea to have regular control plans for FCMs defined at the EU level and stated that those plans should be defined by EU Member States, as this matter should be adapted to the different situations of the EU Member States. Accordingly, EU Member States tend to have different systems for regular control plans. Indeed, in some EU Member States regular control plans for FCMs are defined at the local level (e.g., Finland, Italy, Poland), while in other Member States it is defined at the national level (e.g., Norway, Portugal).

According to the evidence collected during the interviews with NCAs, regular control plans should remain flexible enough to adapt to specific situations and not to be an obstacle to the risk-based approach for the controls, namely, to determine the frequency of checks:

- Many EU Member currently have a risk-based approach for regular control plans, whereby the frequency of checks id determined based on the operations of Business Operators, such as Belgium, Germany, Denmark, Finland, Poland, and Slovakia.
- German NCAs supported regular control plans at the condition it is risk-based, arguing that "it is common approach in food legislation that control should be risk based."
- German NCAs mentioned that national control plans should allow sufficient flexibility to adapt to specific unexpected situations.

In conclusion, the majority of NCAs consulted in EU Member States support regular control plans for FCMs for ensuring safety and enhancing coordination. These plans should ideally include documentary checks, analytical testing and risk-oriented frequency of checks. While there is a call for such plans to be coordinated at the EU level, the approach should be flexible and adaptable to suit the specific situations of individual Member States. The emphasis is on maintaining a balance between standardization and ability to respond to unexpected situations or risks.

1.4.6. Q20. How can Member State competent authorities maximize collaboration, exchange information and ensure coherence of control activities?

EU level Member State competent authorities can maximize collaboration exchange information and ensure coherence of control activities through the establishment of a European IT infrastructure. In specific, when it comes to the governance of such system, stakeholders tend to favor a centralized system, as reported in the OPC analysis where more respondents (n=143, 44%) tended to favor the establishment of a centralized digital system to exchange compliance information.

In the written questionnaires and during the interviews, many NCAs indicated that a common European IT platform/system accessible by competent authorities would further improve collaboration, the exchange of information and ensure coherence of control activities (Austria, Belgium, Estonia, France, Germany, Italy, Lithuania, Poland and Slovakia). Based on the views of the NCAs of those Member States, the role of this EU IT platform would be to collect DoCs and supporting documents from Business Operators

[5] https://eur-lex.europa.eu/eli/reg/2017/625/oj

and would allow to exchange information in the EU and facilitate direct requests for information among Member States.

- The NCAs of Finland and Malta indicated that the Administrative Assistance and Cooperation (AAC) Network could be used to share information and improve collaboration. However, the French NCAs argued that a new EU platform to facilitate direct request among Member States would allow a better reactivity than the platform AAC/iRASFF for simple requests.
- The NCAs in Austria and Germany strongly supported the establishment of a centralized IT system. Furthermore, the Austrian NCA specified that the positive impact of this centralized IT system is conditional upon regulating the uploading of DoC and supporting documents by business operators onto the system, as well as on the cross-border access of all NCAs to this IT system.
- In the online survey, industry representatives have confirmed that a centralized IT infrastructure at the EU level would help maximizing collaboration, exchange information and ensure coherence of control activities. According to the online survey aimed at gathering the views of industry throughout the supply chain:

  - 59% of industry stakeholders who replied to the survey generally agreed that a centralized IT systems can enable improved coordination and collaboration among different entities or organizations within the European Union;
  - 67% of industry stakeholders agreed that a centralized IT systems can help establish standardized and consistent processes across the European Union.
  - 48% of industry stakeholders agreed that a centralized IT systems can provide better data management and analysis capabilities, as data can be consolidated, standardized and processed centrally.
  - Only 34% of industry stakeholders agreed that centralized IT systems can leverage economies of scale by pooling resources, infrastructure, and expertise.

Besides the establishment of a centralized IT infrastructure, the revision of the EU legislation on FCM and a common interpretation among Member States of this legislation appears as essential to maximize collaboration exchange information and ensure coherence of control activities based on the responses from some NCAs to the written questionnaire as argued by the German and Finnish NCAs. The current FCM legislation on FCMs includes indeed loopholes which pose the following challenges for collaboration and information exchange among EU Member States:

- Supporting documentation is not always readily available to be checked by competent authorities as it is not handed down through the supply chain and NCAs can only take action in their own territory (Germany).
- As a result of the different interpretations of the requirements of the current EU legislation, the competent authorities of some EU Member States can refuse to share information from the companies on their territory, which can incentivize other EU Member States not to share information from their companies (Finland).

Some NCAs made other proposals related to coordination among Member States to maximize collaboration exchange information and ensure coherence of control activities:

- Lithuania advised for "Coordinated control plan (as it was in 2019 - Commission Recommendation (EU) 2019/794)";
- Germany mentioned "cooperation of EU Member States in EU projects and coordination at the EU level";
- Italy argued for coordinated EU control campaigns.

- In conclusion, Member State competent authorities can bolster collaboration, information exchange, and coherence of control activities via the establishment of an IT infrastructure for information exchange. This platform would enable the easy exchange of compliance documents and facilitate swift communication. Additionally, revising EU legislation on Food Contact Materials and coordinating control plans and campaigns at the EU level could address existing challenges and further enhance collaboration among Member States.

1.4.7. Q21. Would a legally defined minimum control frequency applicable to controls by MS competent authorities be needed to ensure a high level of compliance?

According to the responses to interviews and written questionnaires, Member State NCAs as well as industry representatives have generally indicated that the FCM legislation should not legally define minimum control

frequency at the EU level applicable to controls by Member States competent authorities to ensure a high level of compliance. In specific, the Belgian and German NCAs informed the Study Team that EU Member States have already established minimum control frequencies. Accordingly, there would not be a need for the determination of such legally defined minimum control frequency at the EU level. The NCAs from Austria argued that "it would not be appropriate measures to legally define minimum control frequency applicable to controls by Member State competent authorities" as it is up to Member States to exercise market surveillance. Accordingly, minimum control frequencies defined at national level would allow Member States to adapt to the specificities and human resources of each country. This statement was seconded by Hungary's NCA.

During interviews, business representatives argued that there is no need for such minimum control frequency defined at the EU level as the current compliance controls are already fulfilling their purpose. This was supported by Silicone Europe, but also by Glass Alliance Europe that also detailed that since the batch of a material that is subjected to compliance checks does not change with time, there is consequently no point in checking it multiple times. Food Drink Europe indicated that business operators already provide all needed information to authorities for compliance verification and that risk assessments already do the work to demonstrate to the consumer that the product is safe. Therefore, they do not see the value in having more checks. According to Flexible Packaging Europe, the definition of minimum control frequency at the EU level would increase the scope of authorities and their workload and therefore represent a burden for EU Member States.

According to some Member State NCAs, the minimum control frequency defined at the national level of EU Member States has the benefit of remaining flexible enough to adapt to the level of risks of business operations and thus is better suited to the risk-based approach of controls adopted by certain EU Member States. This is the case of Belgium, Denmark, Finland, Germany, Poland, Lithuania and Portugal, which have a flexible system to determine the minimum number of control frequency to be carried out for each level of risk according to the risk classification of FCM business operators. For instance, in Poland, where frequency of checks depends on risk assessment: "the proposed frequency of controls are indicated by risk category: 1) high risk (control at least every 12 months for production plants and at least once every 18 months for trading entities), 2) medium risk (control at least once every 18 months of production plants ana at least once every 24 months for trading entities, 3) low risk (control at least once every 24 months for production plants and at least once every 36 months for trading entities)" (Written questionnaire from Polish NCAs).

In conclusion, based on the responses from both Member State National Competent Authorities and industry representatives, there seems to be a consensus that there is no need for a legally defined minimum control frequency at the EU level to ensure a high level of compliance. Member States are already exercising their authority in market surveillance with their established minimum control frequencies. Furthermore, business representatives underscore that current compliance controls are effectively serving their purpose. Legally defining a minimum control frequency at the EU level could potentially increase workload burdens and add unnecessary checks, as robust risk assessment procedures are already in place. Instituting a nationally defined minimum control frequency allows for flexibility and adaptability to suit the specific risks and resource provisions of each country. It also enables a risk-based approach to controls, currently adopted by several Member States, which provides for appropriate and proportionate checks, thereby balancing the need for safety compliance and operational efficiency.

1.4.8. Q22. What aspects would require controls to maximize compliance with a low relative burden to MS competent authorities?

During the consultations, stakeholders generally did not identify issues with the current system of official controls stating that it is indeed effective. They have generally not raised the need for additional areas to be subjected to controls to maximize compliance of FCM products. Nevertheless, during the interviews, the Study Team was informed that several of the consulted representatives of industries had very few or even no direct experience of official controls from National Competent Authorities (Metal Packaging Europe, Plastics Europe, FEICA, EUPIA, CEPE, Food Drink Europe, Silicones Europe, CEFIC, Flexible Packaging Europe). Accordingly, official controls would happen rarely and, in those occasions, the provision of the requested compliance and/or additional documentation by the business operator would suffice. In the written questionnaires, Member States have highlighted the need of trainings on specific areas of the FCM sector that would provide inspectors with higher capabilities to interpret the compliance and supporting documentation provided to the by FCM business operators. For instance, the German NCA mentioned the need for specialized knowledge in the field of toxicology as well as chemical analysis. This information was confirmed by part of the industry during the interviews (Metal Packaging Europe, FEICA, EUPIA, CEPE). Notably, during one interview (CerameUnie), it was raised the need to apply additional controls on the importers of finished products (in this case, ceramics products) coming from outside the EU. Accordingly,

such importers are not subjected to enough controls and this would pose a danger to the internal market for EU producers.

In conclusion, while the present system of official controls is reported as generally effective, the maximization of FCM product compliance with a low burden to Member State competent authorities could be improved in a few key areas. to maximize compliance with minimal burden, areas that require controls include specialized training for inspectors in fields like toxicology and chemical analysis, and increased scrutiny on importers of finished products from outside the EU. These measures aim to improve interpretation of compliance documents and ensure imported products meet EU standards.

1.4.9. Q23. Are there any specific strategies that could help improving compliance?

During the interviews, stakeholders have rather refrained from proposing additional strategies to improve compliance of FCM materials, aside from the proposed establishment of an IT infrastructure for information exchange and verification of compliance. During interviews, the Study Team has generally registered strong interest of stakeholders for the revision of the other pillars of the legislation, which would accordingly have a stronger impact on improving the functioning of the supply chain, as well as compliance. This is the case of some industry representatives that have proposed to create a positive list of non-harmonized material and therefore have the requirement of a DoC for such materials (Metal Packaging Europe, EUPIA, FEICA). Accordingly, this would ensure that information is exchanged in a standardized way even for non-harmonized materials. Metal Packaging Europe proposed to establish an obligation for raw material producers to provide information to the other actors in the supply chain, whereas EUPIA called for clarifying testing needs of materials for compliance verification. Others have proposed the development of common guidelines for non-harmonized products (Denmark proposed to follow the example of the Nordic Council of Ministers), or that industry guidelines are officially endorsed in EU legislation (FEICA). This would accordingly benefit the provision of information in a structured way, as well as SMEs in carrying out their compliance work.

In conclusion, beyond the proposed IT infrastructure for facilitating information exchange and compliance verification, stakeholders have suggested other strategies to improve compliance of FCM. Stakeholders suggest creating a positive list for non-harmonized materials, obligating raw material producers to provide more information, clarifying testing requirements, and officially endorsing industry guidelines in EU legislation. These strategies would establish standardized processes, strengthening the supply chain and easing compliance especially for SMEs.

1.4.10. Q24. Could for instance a QR code referring to information on the composition of an FCM marked with it increase compliance and facilitate controls?

Based on the data collected during the first phase of consultations, it appeared that a QR code referring to information on the composition of an FCM marked with it is unlikely to increase compliance and facilitate controls by enforcement authorities. According to the open public consultation (OPC), a majority of respondents (42%) disagreed with the proposal of placing a QR code or equivalent on FCM articles providing information to users of FCMs, including to control authorities for enforcement purposes, and 23% of respondents were neutral with regards to this matter. In some position papers submitted in the framework of the OPC, stakeholders have questioned the relevance of having the same information in a QR code for authorities, business operators and consumers when all of them have different information needs (Swedish Food Federation), as well as challenges with sharing safety information with a tool that is meant for traceability of the products' name and bath numbers (Mitsubishi Chemical Europe GmbH). The OPC results are confirmed by the Online Survey carried out by the Study Team: most industry stakeholders who replied to the survey disagree with the idea of having a QR code or equivalent on each individual FCM article to give information to users of FCMs, including control authorities for enforcement purposes: 66% agreed to a low extent or to a very low extent with this idea.

From the side of the NCAs, the proposal of having a QR to increase compliance and facilitate controls is not supported by the French NCAs, which argues that the QR would have a rather negative impact on compliance of the industry and controls from enforcement authorities for the following reasons:

- The QR code is only a communication channel would require compliance documents to be transmitted by business operators along the supply chain to work and business operators who do not currently provide compliance documents would be unlikely to use the QR code if it is introduced.
- While compliance documentation is not systematically currently checked during controls, a QR code would add an additional step of verification of compliance for authorities who would need to scan the QR code to access the declaration of compliance and thus decrease the likelihood they would check documents.

Although some NCAs (Austria, Poland, Germany, and Hungary) tended to support the idea that a QR code would help to check compliance and facilitate controls in the interviews and written questionnaires, most of those views are rather nuanced. Many NCAs who support the use of QR code claimed for instance the following points regarding this proposal:

- The use of a QR code is not the priority which is to have a database to find the documents (Austria);
- The usefulness of the QR code would depend on whether the information is received easily and whether it allows knowing what substance were used to create the FCM, but it is uncertain this is feasible (Germany);
- While it is not clear at the moment what the QR code should be linked to, it would be facilitate controls if "the QR-Code lead to a central point, where business operators can store compliance/ supporting/ other documentation". On the other, it would not be useful if the QR code leads to a checklist (Germany).

- In the second phase of consultations, namely when presented with the developed Policy Options and with the possibility of integrating them with QR codes, interviewed Member States and industry representatives tended to agree that a QR code technology could be beneficial for FCM compliance controls (Finland, Slovakia, Slovenia, Norway, Netherlands, Belgium, Estonia, CEI-Bois, MPE, Plastics Europe). However, ensuring industry readiness and cooperation would be crucial for successful implementation (Portugal).

While there are varying opinions and concerns surrounding the use of QR codes for FCM compliance and controls, the overall trend suggests a potential for QR code technology to be beneficial. Certain Member States (Austria, Poland, Germany, Hungary, Finland, Slovakia, Slovenia, Norway, Netherlands, Belgium, Estonia) and industries (CEI-Bois, MPE, Plastics Europe) see the advantages of QR codes in improving access to information and streamlining controls. However, it is clear that successful implementation would require addressing industry readiness, ensuring the QR codes lead to relevant and accessible information, and not overlooking the need for a centralized database as a primary priority.

While initial skepticism was present, the consultations indicate that a QR code system referring to FCM composition information could indeed increase compliance and facilitate controls. The key will be to address the concerns raised, ensure clarity in the information provided, and work towards industry cooperation for effective implementation.

In more practical terms, though the process of authentication and registration of products by starting and intermediate manufacturers remains the same, instead of selecting materials, each manufacturer in the supply chain generates a unique QR code for each of its products. In this way, customers can list the materials contained in their products by scanning the QR codes of the components transmitted by their suppliers. The information retrieval by hand is replaced by scanning a QR code. The QR code generated for the final FCM allows authorized users (authorities or Delegated bodies under Official Control Regulation 2017/625) to open the history of the FCM for official controls: all the suppliers in the product's manufacturing chain, all the substances and intermediary products entering the supply chain, as well as all the DoCs and supporting information can then be accessed. With a QR code, withdrawing information from the platform for compliance would be much easier.

1.5. IT infrastructure required for information exchange - Assessment

1.5.1. Q25. What would be the advantages and disadvantages of the different options?

The Study Team identified advantages and disadvantages of centralized and decentralized IT systems already at Inception report stage (see section 2.3.1. of the Inception Report). During consultation, the matter was further explored with stakeholders.

The advantages of introducing an IT infrastructure on a centralized system (Policy Option 1) can be listed as follows:

- **Enhanced coordination and collaboration**: By having a single system that serves multiple entities, such as Member States or agencies, it can facilitate seamless data sharing, communication, and cooperation, leading to improved efficiency and effectiveness in decision-making and operations. Stakeholders responding to the online questionnaire were in strong agreement with this statement (n=59, 57%). Almost all Member States responding to the question in the written questionnaire (n=19 out of 20) agreed that the system would enhance coordination and collaboration.

- **Streamlined and consistent processes:** Centralized IT systems can help establish standardized and consistent processes across the European Union. This can lead to harmonization of procedures, data formats, and reporting requirements, resulting in increased efficiency and reduced complexity in operations. It can also simplify regulatory compliance and facilitate uniformity in policies and practices. A large majority of respondents to the online survey (n=67, 66%) agreed that a centralized IT system can help establish standardized and consistent processed across the EU. Almost all Member States responding to the question in the written questionnaire (n=19 out of 20) agreed that the system would improve processes in terms of standardization and consistency.
- **Economies of scale:** Centralized IT systems can leverage economies of scale by pooling resources, infrastructure, and expertise. This can potentially result in cost savings through shared procurement, reduced duplication of efforts, and optimized resource utilization. It can also enable better utilization of specialized skills and expertise, leading to improved outcomes and cost-effectiveness. Respondents were rather divided on assessing the possible emergence of economies of scale: 45 respondents (43%) were not sure, 34 respondents (33%) agreed or strongly agreed, and 25 respondents (24%) disagreed or strongly disagreed. Most Member States responding to the question in the written questionnaire (n=15 out of 19) agreed with this statement.
- **Improved data management and analysis:** Centralized IT systems can provide better data management and analysis capabilities, as data can be consolidated, standardized, and processed centrally. This can enable improved data quality, integrity, and consistency, leading to better cross-referencing, decision-making and policy formulation. Centralized systems may also provide enhanced data analytics capabilities for deriving insights and actionable intelligence from large datasets. More respondents to the online questionnaire agreed with this item (n=49, 48%). Almost all Member States responding to the question in the written questionnaire (n=19 out of 20) agreed with this statement.
- **Better service delivery:** Centralized IT systems can facilitate improved service delivery to citizens, businesses, and other stakeholders across the European Union. Centralized systems can enable streamlined access to services, reduced duplication of efforts, and standardized service levels since a unique administrator will oversee all updates, fixes, and improvements. This can result in improved customer experience, satisfaction, and trust in the IT systems and services provided by the European Union. Respondents were rather divided on whether a centralized system could facilitate improved service delivery to citizens: 37 respondents (36%) were not sure, 37 respondents (36%) agreed or strongly agreed, and 30 respondents (29%) disagreed or strongly disagreed. Most Member States responding to the question in the written questionnaire (n=14 out of 19) agreed that the system would lead to better service delivery.
- **Enhanced security and privacy:** Centralized IT systems can potentially offer better security and privacy measures through centralization of control and governance. Robust security measures, such as access controls, encryption, and authentication, can be implemented centrally to protect data and systems from unauthorized access, breaches, or cyber threats. Centralized systems may also have better oversight and monitoring mechanisms to ensure compliance with data protection regulations. More respondents to the online questionnaire were not sure about this impact (n=42, 40%), compared to those who confirmed it (n=32, 31%). Almost all Member States responding to the question in the written questionnaire (n=13 out of 18) agreed that the system would enhance security and privacy.

The disadvantages of introducing an IT infrastructure on a centralized system can be listed as follows:

- **Lack of flexibility and adaptability:** Centralization could result in a one-size-fits-all approach, which may not be suitable for the diverse needs and requirements of Member States. It could limit the ability of Member States to customize IT solutions and services to their specific local conditions, such as language differences, cultural nuances, and regulatory environments. This lack of flexibility and adaptability could lead to inefficiencies and suboptimal outcomes. A large majority of respondents to the online survey (n=67, 66%) expressed agreement with the fact that centralization could lead to a one-size-fit all approach. Most Member States responding to the question in the written questionnaire (n=10 out of 19) disagreed with this statement.
- **Complex governance and decision-making:** A centralized IT system could involve complex governance and decision-making processes. Centralized decision-making could lead to delays, bureaucracy, and challenges in accommodating the interests and perspectives of all Member States. It could also result in challenges in coordinating efforts, managing conflicts, and achieving consensus on IT policies, strategies, and regulations. Most respondents to the online survey (n=70, 68%)

expressed agreement with the fact that governance and decision-making processes in a centralized system may be rather complex. Most Member States responding to the question in the written questionnaire (n=13 out of 19) agreed with the statement about complex governance and decision making.

- **Data privacy and sovereignty concerns:** Centralization could raise concerns about data privacy and sovereignty. Centralized storage and management of data could lead to concerns about data privacy, security, and potential misuse of data. Member states may have concerns about their sovereignty and control over their own data, as well as the risk of unauthorized access or data breaches in a centralized system. A large number of respondents to the online questionnaire strongly agreed (n=47, 45%) or agreed (n=30, 29%) that centralization may lead to concerns about data privacy and sovereignty. Most Member States responding to the question in the written questionnaire (n=11 out of 19) agreed with this statement.
- **Single point of failure:** A centralized IT system could present a risk of a single point of failure. If the centralized system experiences a technical glitch, outage, or cyber-attack, it could disrupt the entire IT infrastructure and services across the EU. This could result in widespread disruptions, loss of data, and downtime, affecting businesses, citizens, and public services. A large majority of respondents to the online questionnaire (n=82, 79%) agreed that a centralized system could present a risk of a single point of failure. Most Member States responding to the question in the written questionnaire (n=16 out of 23) agreed that the system may present such a risk.
- **Potential inequities and disparities:** Centralization could result in potential inequities and disparities among Member States. Member states with different levels of IT infrastructure, capabilities, and resources may face challenges in accessing and utilizing centralized IT services on an equal footing. This could exacerbate existing disparities among Member States and hinder equitable access to IT resources and services. Respondents to the online survey were not convinced about potential inequities and disparities among Member States as a result of a centralized system: 42 respondents (36%) agreed with this statement, whereas 32 respondents (31%) did not express an opinion and 30 respondents (29%) did not agree. Most Member States responding to the question in the written questionnaire (n=13 out of 20) disagreed that the system may lead to potential inequities and disparities.
- **Reduced innovation and competition:** Centralization could potentially reduce innovation and competition among IT providers. A centralized IT system could limit opportunities for local IT providers and startups, reducing competition and innovation. This could result in reduced diversity of IT solutions and services and hinder the development of new technologies and approaches. Respondents to the online questionnaire were divided on this matter: 38 respondents (36%) agreed, 25 respondents (24%) disagreed, and 41 respondents (39%) did not express an opinion. Member States responding to the question in the written questionnaire were divided between those that disagreed that the system may lead to reduced innovation and competition (n=9 out of 19) and those that could not take a position (n=8 out of 19).
- **Limited local empowerment and ownership:** A centralized IT system may limit the empowerment and ownership of Member States over their IT strategies and solutions. Member states may have less autonomy in designing and implementing IT solutions that are best suited to their local needs and requirements. This could result in reduced local engagement, participation, and ownership, leading to challenges in governance and decision-making processes. More respondents either did not express an opinion (n=51, 50%) or agreed (n=38, 37%) with this statement. Member States responding to the question in the written questionnaire were divided between those that disagreed that the system may limit local empowerment and ownership (n=8 out of 19) and those that could not take a position (n=6 out of 19).

The advantages of introducing an IT infrastructure on a decentralized system can be listed as follows:

- **Flexibility and autonomy:** Decentralized IT systems can allow Member States to have flexibility and autonomy in managing their own IT infrastructure, applications, and services. This can enable them to adapt to their specific needs, requirements, and priorities, and make decisions that are tailored to their local context. Respondents to the online questionnaire were divided on this statement between 46 respondents (46%) that agreed that such a system could guarantee enhanced flexibility and autonomy to Member States, and 45 respondents (45%) that did not express an opinion. More Member States responding to the question in the written questionnaire (n=10 out of 18) agreed with this statement.

- **Customization and local innovation:** Decentralized IT systems can foster local innovation and customization, as Member States may have the freedom to develop and implement IT solutions that are best suited to their unique circumstances. This can result in diverse approaches, ideas, and solutions, leading to potential benefits in terms of efficiency, effectiveness, and relevance. The responses collected through the online survey are inconclusive as a majority of respondents did not express an opinion on this matter (n=60, 59%), the rest were equally divided between those that agreed (n=20, 20%) and those that disagreed with this statement (n=21, 21%). Member States responding to the question in the written questionnaire were divided between those that disagreed that the system may foster customization and local innovation (n=6 out of 17) and those that could not take a position (n=6 out of 17).
- **Local skills development and capacity building:** Decentralized IT systems can provide opportunities for local skills development and capacity building, as Member States may need to develop their own IT expertise, capabilities, and workforce. This can result in local talent development, knowledge sharing, and increased capabilities in managing IT systems and services. A majority of respondents to the online questionnaire did not express any opinion on whether the system could provide opportunities for local skills development (n=61, 60%). More respondents agreed with this statement (n=26, 26%) compared to those that disagreed (n=14, 14%). Member States responding to the question in the written questionnaire were divided between those that disagreed that the system could provide such opportunities (n=7 out of 19) and those that agreed (n=7 out of 19).
- **Faster implementation and decision-making:** Decentralized IT systems can potentially lead to faster implementation and decision-making, as Member States may have more agility and flexibility in making IT-related decisions and taking action. This can result in quicker response times, faster adoption of new technologies, and more efficient IT operations. Most respondents to the online questionnaire did not express any opinion on whether the system could provide opportunities for local skills development (n=60, 59%). More respondents agreed with this statement (n=23, 23%) compared to those that disagreed (n=18, 18%). More Member States responding to the question in the written questionnaire (n=9 out of 17) disagreed with this statement.
- **Cost efficiency and resource optimization in maintenance:** Decentralized IT systems can potentially offer cost efficiency and resource optimization, as Member States may have the flexibility to manage their IT budgets, investments, and procurement processes. This can result in optimized resource allocation, reduced duplication of efforts, and potential cost savings in the long term. A majority of respondents to the online questionnaire did not express any opinion on whether the system could provide opportunities for local skills development (n=57, 56%). More respondents disagreed with this statement (n=28, 28%) compared to those that agreed (n=16, 16%). More Member States responding to the question in the written questionnaire (n=10 out of 18) disagreed that the system could lead to cost efficiency and resource optimization in maintenance.
- **Adaptable to local regulations and policies:** Decentralized IT systems can enable Member States to adapt to their own local regulations and policies, as they may have the flexibility to implement IT solutions that are compliant with their own regulatory requirements. This can result in better adherence to local laws and regulations and reduce the risk of non-compliance. Most respondents to the online questionnaire did not express any opinion on whether the system could provide opportunities for local skills development (n=54, 53%). More respondents agreed with this statement (n=34, 34%) compared to those that disagreed (n=13, 13%). More Member States responding to the question in the written questionnaire (n=12 out of 18) agreed that the system would be able to adapt to local regulations and policies.
- **Enhanced resilience and redundancy:** Decentralized IT systems can offer enhanced resilience and redundancy, as Member States may have their own IT infrastructure and services. This can reduce the risk of single points of failure and minimize the impact of IT disruptions or incidents, as Member States can potentially rely on their own resources and capabilities. Most respondents to the online questionnaire did not express any opinion on whether the system could provide opportunities for local skills development (n=63, 62%). Slightly more respondents agreed with this statement (n=20, 20%) compared to those that disagreed (n=18, 18%). Member States responding to the question in the written questionnaire were divided between those that disagreed with this statement (n=7 out of 19) and those that agreed (n=8 out of 19).

The disadvantages of introducing an IT infrastructure on a decentralized system can be listed as follows:

- **Lack of standardization:** A decentralized IT system across the EU may result in a lack of standardization in terms of technological infrastructure, data formats, and protocols. This can lead to interoperability challenges, making it difficult for different systems to communicate and exchange information seamlessly. It may also hinder the development of common IT solutions and services that could benefit the entire EU. A large majority of respondents (n=76, 76%) to the online survey agreed that such a system would result in a lack of standardization. Almost all Member States responding to the question in the written questionnaire (n=17 out of 18) agreed with this statement.
- **Inconsistent data protection:** Decentralized IT systems may result in varying data protection standards across different Member States of the EU. This can create challenges in terms of compliance with the General Data Protection Regulation (GDPR), the EU's data protection framework, leading to potential legal and regulatory issues. It may also impact the privacy and security of personal data, as different Member States may have different approaches to data protection. A large majority of respondents (n=62, 62%) to the online survey agreed that such a system would result in varying data protection standards. Most Member States responding to the question in the written questionnaire (n=15 out of 18) agreed with this statement.
- **Higher initial costs:** Decentralization can result in increased costs related to IT infrastructure, development, and maintenance. Each member state may need to invest in building and maintaining its own IT systems, which can lead to duplication of efforts and increased costs. Coordination and harmonization of IT systems across Member States may also require additional resources and efforts. Most respondents (n=57, 57%) to the online survey agreed that a decentralized system would result in increased costs. Most Member States responding to the question in the written questionnaire (n=14 out of 18) agreed with this statement.
- **Fragmented governance:** A decentralized IT system may result in fragmented governance and decision-making processes. Coordination among Member States may be challenging, leading to delays in decision-making, lack of consistency in policies, and difficulties in implementing common IT initiatives or strategies. This can hinder the ability of the EU to respond quickly and effectively to technological changes and evolving IT requirements. A large majority of respondents (n=65, 65%) to the online survey agreed that such a system would result in fragmented governance and decision-making processes. Most Member States responding to the question in the written questionnaire (n=13 out of 17) agreed with this statement.
- **Limited scalability and innovation:** Decentralized IT systems may lack the scalability and innovation potential of a centralized system. Smaller Member States with limited resources may face challenges in keeping up with rapidly evolving technologies and innovations, resulting in an uneven playing field for businesses and citizens across the EU. It may also limit the ability of the EU to drive digital transformation and innovation at a pan-European level. Compared to those that disagreed (n=14, 14%), more respondents to the online survey agreed that such a system may lack the scalability and innovation potential vis-à-vis a centralized system (n=40, 40%). Most Member States responding to the question in the written questionnaire (n=15 out of 18) agreed with this statement.
- **Introduction of inequalities:** A decentralized IT system may result in inequalities due to disparate technological capabilities and resources among the countries or industries. Additionally, larger countries/corporations with more influence and financial/technological resources could potentially impose their decisions over the smaller and less experienced countries/corporations on these matters.

1.5.2. Q26. What would the overall cost be, including a breakdown of costs: (i) Administrative and compliance costs for large businesses, (ii) Administrative and compliance costs for SMEs, (iii) Any costs for MS, (iv) Any costs for EU?

The breakdown of administrative and compliance costs for the FCM IT System should be distinctly evaluated for each Policy Option. This is necessary as every Policy Option assigns a different stakeholder as the system's administrator, which inherently results in varying investment requirements from all involved parties.

- **For large businesses**
    - Policy Options 1 and 2 → contribute to the creation of the centralized data platform by providing human resources to collaborate with the EU and other Industries to establish standardized and consistent processes across the European FCM market and produce harmonized procedures, data formats, and reporting requirements for the system.

- Dedicate time and resources to input all the data about the FCM products manufactured or used in the system to ensure its integrity and respond timely to demands for additional elements and facilitate compliance verification.
- Policy Option 3 → since businesses will act the system's administrator, they would bear most significantly the costs of the FCM IT System.
- To promote equity within the system, we recommend that costs should be allocated on a progressive basis between businesses depending on their revenues (an identical % share of their revenues being dedicated to the FCM IT system may represent a greater burden for an SME than for a large business).

- Make human resources available to collaborate with the EU and Industries to establish standardized and consistent processes across the European FCM market and produce harmonized procedures, data formats, and reporting requirements; and ensure the day-to-day management of the system in order to ensure seamless data sharing, communication, and cooperation.
- Larger and more technologically advanced businesses should also dedicate resources to share knowledge and assists SMEs in the implementation of the system.
- Dedicate time and resources to input all the data about the FCM products manufactured or used in the system to ensure its integrity and respond timely to demands for additional elements and facilitate compliance verification.
- Provide financial resources to fund the development of the national data-platform (hardware and software, training, etc.) and its running of the long-run (updates, fixes, and improvements, security and threat responses, helpdesk, etc.).
- They should also, on their own or as part of industry associations, leverage their collective bargaining power to negotiate cost-effective contracts when commissioning the IT system, and provide SMEs with direct channels to funding sources, like sector-specific grants or private investors, which can be utilized to offset system costs.

- **For SMEs**

  - Policy Options 1 and 2 → contribute to the creation of the centralized data platform by providing human resources to collaborate with the EU and other Industries to establish standardized and consistent processes across the European FCM market and produce harmonized procedures, data formats, and reporting requirements for the system.
  - Dedicate time and resources to input all the data about the FCM products manufactured or used in the system to ensure its integrity and respond timely to demands for additional elements and facilitate compliance verification.
  - Policy Option 3 → since businesses will act the system's administrator, they would bear most significantly the costs of the FCM IT System.
  - To promote equity within the system, we recommend that costs should be allocated on a progressive basis between businesses depending on their revenues (an identical % share of their revenues being dedicated to the FCM IT system may represent a greater burden for an SME than for a large business).
  - Make human resources available to collaborate with the EU and Industries to establish standardized and consistent processes across the European FCM market and produce harmonized procedures, data formats, and reporting requirements; and ensure the day-to-day management of the system in order to ensure seamless data sharing, communication, and cooperation.
  - Dedicate time and resources to input all the data about the FCM products manufactured or used in the system to ensure its integrity and respond timely to demands for additional elements and facilitate compliance verification.
  - Provide financial resources to fund the development of the national data-platform (hardware and software, training, etc.) and its running of the long-run (updates, fixes, and improvements, security and threat responses, helpdesk, etc.).

- **For Member States**

  - Policy Option 1 → Member States will contribute to the creation of the centralized data platform by providing human resources to collaborate with the EU and other Member States to establish

standardized and consistent processes across the European FCM market and produce harmonized procedures, data formats, and reporting requirements for the system.
- Policy Option 2 → the National entities that will act the system's administrator would bear most significantly the costs of the FCM IT System:
- Make human resources available to collaborate with the EU and other Member States to establish standardized and consistent processes across the European FCM market and produce harmonized procedures, data formats, and reporting requirements; and ensure the day-to-day management of the system in order to ensure seamless data sharing, communication, and cooperation. Larger and more technologically advanced States should also dedicate resources to share knowledge and assists smaller and less advanced States in the implementation of the system.
- Dedicate resources to manage and analyze the data produced by the system.
- Provide financial resources to fund the development of the national data-platform (hardware and software, training, etc.) and its running of the long-run (updates, fixes, and improvements, security and threat responses, helpdesk, etc.).
- Policy Option 3 → Member States could support to SMEs implementation of the system by offering subsidies or incentives for system utilization within their jurisdiction; and by offering local training initiatives to bridge the gap between technology and users, tailored to the specific regional needs and linguistic diversity.

- **For the EU**
  - Policy Option 1 → the EU entity that will act the system's administrator would bear most significantly the costs of the FCM IT System:
  - Make human resources available to establish standardized and consistent processes across the European FCM market and produce harmonized procedures, data formats, and reporting requirements; and ensure the day-to-day management of the system in order to ensure seamless data sharing, communication, and cooperation. Dedicate resources to manage and analyze the data produced by the system.
  - Provide financial resources to fund the development of the System (hardware and software, training, etc.) and its running in the long-run (updates, fixes, and improvements, security and threat responses, helpdesk, etc.).
  - Policy Option 2 → the EU will contribute to the creation of the centralized data-hub (PO2A) or to the instauration of interoperability (PO2B) that will connect the National data platforms:
  - As for PO1, make human resources available to establish standardized and consistent processes across the European FCM market and produce harmonized procedures, data formats, and reporting requirements for the data-hub or interoperability.
  - Provide financial resources to fund the development and run of the data-hub or interoperability.
  - Policy Option 3 → the EU will contribute during the implementation phase to establish standardized and consistent processes across the European FCM market and produce harmonized procedures, data formats, and reporting requirements that will be applied by the Industries who act as administrators.

1.5.3. Q27. How do these costs compare with the current costs and also with the turnover and profitability of each type of business?

Given the inexistence of any IT system for tracking and compliance verification of Food Contact Materials, either at the EU level or at National/Industry level, the comparison of costs is limited.

Currently, costs are incurred for the FCM supply chain stakeholders due to the lack of any IT system for tracking FCM data, in the following ways:

- Member States : NCAs require extensive time to conduct verifications of compliance, resulting in great inefficiencies and a sub-optimal allocation of their human resources.
- FCM Manufacturers: require extensive time to trace the entire FCM supply chain in order to gather the necessary data for compliance verifications (DoCs and supporting documentation).

These indirect costs, both financial and human (inefficient time allocation) result in a lack of transparency that generates losses of crucial information for the entire FCM system.

All FCM businesses currently have internal IT infrastructure but lack proper information exchange infrastructure except emails, which do not offer sufficient transparency and quality of data.

There is therefore a high opportunity cost of not developing a complete and reliable IT system for FCM compliance verification, given the high aggregated indirect costs across the European market of not having transparent and readily-available data on FCM products.

1.5.4. Q28. What are the potential long-term burden and cost reductions of such a system for each type of business and for Member States and the Union?

The stakeholders who will bear the potential long-term burden of the system will be those who take on the role of being its administrators, which will differ based on the chosen Policy Option (EU entity for PO1, Member States for PO2 and Industries for PO3). This administrator will face the burden of:

- Maintaining and upgrading the system in the long-term to ensure that it remains compliant with any new European and National regulations on FCM products
- Training new users of the system, and offering continuous learning opportunities to "refresh" the knowledge of existing users and train them to use any new features of the system
- Ensuring the system's security, responding to threats, and avoiding data breaches.
- Remaining updated on all relevant technologies that could potentially replace the IT architecture described in this report, as it may become obsolete over the years, and new technologies may offer relevant solutions.

As detailed in Question 27, the implementation of the FCM IT System will reduce the following costs, supporting the 5 "pillars" of the revised FCM legislation:

- Reduce the time needed to access relevant and complete information, making compliance verifications more efficient for all stakeholders (satisfying "pillars" D, E and F regarding *Information Exchange, compliance and enforcement of FCMs*)
- Consequently, enhance the safety of all FCM products used in the EU market (satisfying "pillars" A, B and C regarding *Safety and Sustainability of FCM*)

1.5.5. Q29. What are the potential options for funding the development and upkeep of such a system?

It exists a diverse array of options to fund the development and upkeep of the IT system. According to interviews with the European Commission (DG SANTE, DG GROW, EFSA, ECHA), development and upkeep of the system should be funded through EU funds. This position was confirmed by the following interviewed Member States: Germany, Hungary, Denmark, France, Poland. Other potential funding avenues may include public-private partnerships, with the private sectors focusing on technology development. Grants, subsidies, and user fees may also be utilized, and in some cases, national contributions from Member States or external funding sources.

This question is further developed in section 4.3.1 of the report.

1.6. IT infrastructure required for information exchange - Assessment

1.6.1. Q30. What would the pathways to implementation look like and how long would that take in practice?

As thoroughly presented in the report, the implementation of an FCM IT system will first begin with completing the pre-conditions, such as understanding the stakes and context, defining the appropriate policy option, choosing a funding and economic model, ensuring stakeholder engagement and anticipating the availability of needed resources. Second, the actual implementation of the system will go through 5 major phases: understanding of context and future users needs, defining the business processes and the technology to support them, designing and testing the system, deploying the system and finally checking its effectiveness and maintaining it. The actors, outcomes and timeline are detailed in section 4.3.2 of the report.

1.6.2. Q31. What would the main challenges and possible burdens associated with it be?

On top of the advantages and disadvantages for each Policy Option discussed under Q25 (section 1.5.1), the European Commission may encounter challenges related to the implementation of an IT infrastructure for information exchange and verification of compliance. These challenges span technical and non-technical domains, encompassing issues such as safeguarding data privacy and security in compliance with GDPR, standardizing heterogeneous data formats, achieving interoperability with diverse stakeholder systems, ensuring data accuracy and trustworthiness, and scaling the infrastructure to accommodate the complexity of the supply chain. Additionally, managing the considerable costs, navigating complex regulatory compliance requirements, and overcoming resistance to change among stakeholders are also probable hurdles. Addressing data ownership and governance, maintaining infrastructure reliability, and safeguarding against cybersecurity threats are also vital considerations. Furthermore, an investment in training and skills development is to be foreseen, as well as addressing cross-border trade complexities, and assessing the environmental impact while planning for long-term infrastructure maintenance and evolution. Tackling these challenges necessitates a comprehensive strategy, collaboration with stakeholders, and continuous adaptation to meet the evolving needs of the FCM supply chain and regulatory landscape.

More details can be found in section 4.3 of the report (Impact Assessment and Cost Assessment).

2 Detail of Implementation Pathways

You will find below technical details of the implementation pathways of the FCM IT System:

1. System Architecture Design:
    - **Data flows:** design the overall architecture of the information exchange system and define the path that data will take from its initial entry point into the system, through the processes and transformations, all the way to its final output. This flow shall allow for systematic handling and tracking of data, making it useful in monitoring, quality control, and error detection.
    - **Decide on the technology stack, depending on the PO:**
        - ➔ PO1: whether the centralized system managed by an EU body will be hosted in already operating EC servers (which would facilitate its management and take advantage of possible economies of scale and simplified set-up, as well as connections with other EU databases and systems in the future), or in any other server located in the EU that are not already operated by an EC entity. Since all the system's data will be located in a single platform, servers and data flows should aim to optimize traffic, given the high network traffic expected that could strain system performance, as well as security to avoid the risks incurred by having a single point of failure.
        - ➔ PO2a, 2b and 3: the FCM IT system will be decentralized and hosted across several servers. Thus, the different Member States (PO2) or Industry consortiums (PO3) will need to decide whether the system will be hosted in already existing servers, and in this case which MS/IC will bear the associated costs of running these servers. In the case of PO2a, the same questioning as the one for PO1 will be applied for the creation of the central data hub. With the system's data being divided across several platforms, servers and data flows should aim to optimize interoperability and connectivity between the different servers and focus to ensure consistency and integrity of data.
          At the National/Industry level, the decision-makers will also need to decide on what local stakeholders will be responsible for setting up the servers and data platforms.

          Strong interoperability standards will have to be developed to ensure the smooth transmission of data between the servers and platforms.

2. Security and Privacy:
    - **End-to-end data Encryption**: select a robust encryption algorithm that meets EU data protection standards (for instance, the Advanced Encryption Standard Algorithms are widely recognized for their security) that will immediately encrypt data once it is inputted in the

system. This encryption will apply to data at rest, stored within the system, and data in transit between users or systems. Upon entering or leaving the system, the data should be encrypted and only decrypted when it reaches the approved recipient. This emphasizes the need for a strong Access Attribution and Control, and encryption keys management, so that only authorized users may access the confidential FCM information. The administrator should also have processes in place to rotate secured keys periodically to reduce the risk of compromission.
This will prove critical to prevent unauthorized access to data if there is a security breach, and will be especially relevant for PO2a, 2b and 3, given the significant data transfers that will occur between the multiple data platforms and databases.

- **Firewalls**: select a firewall solution (given the open nature of the system, a software or cloud-based solution is more recommended than a hardware-based one) that suits the system's requirements. This firewall should be positioned between the internal FCM IT network and any untrusted external networks (such as stakeholders' IT systems, be they National bodies or corporate entities) to monitor and control incoming and outgoing network traffic.
Firewalls should be regularly updated, and logs monitored for any suspicious activity. Periodic security audits will be crucial for maintaining robust system security. The firewall setup should ideally be a part of a multi-layered defense strategy that works in tandem with other security measures like Intrusion Prevention Systems (IPS), secure encryption, and consistent employee cybersecurity education.

- **Define SSO and sign-in parameters** depending on the best practices for security, and profile assignation by the admin.
- Implement a **security breach incident response plan**: identify an incident response team with clear roles and responsibilities (including IT, legal, and communications personnel from the various stakeholders) and define a plan outlining the steps to be taken in the event of a security breach, which should include the following:
    - ➔ Identify the incident and its potential causes.
    - ➔ Contain the breach.
    - ➔ Eradicate the threat.
    - ➔ Recover data and systems.
    - ➔ Conduct a post-incident analysis and establish guidelines/best practices to avoid this breach from re-occurring.
    - ➔ Notify the affected parties and regulatory authorities (including the Data Protection Authority).

3. Interoperability Standards:
    - Choose among several possible levels and types of interoperability standards for the FCM IT system to ensure seamless communication between different systems and platforms:
        - ➔ Syntactic Interoperability to focus on data formatting and communication protocols to ensure data can be exchanged correctly. Standards like XML and JSON are commonly used for data exchange formats, while communication protocols may include HTTP, REST, or SOAP → this interoperability should be emphasized for **Policy Options 2b and 3**: given their decentralized nature, this type of interoperability would facilitate the adherence to common data formats and communication protocols that ensure that the system's data structure and format is universally understood, and therefore exploitable by all the stakeholders at all stages of the process. If this option is chosen, all data in the system must be coded in the same data language and format (for instance, XML or JSON), that must be decided.
        - ➔ Semantic Interoperability to ensure that the meaning of data is preserved during exchanges between different systems. Standards like RDF and OWL are employed in making data understandable across diverse systems.
        - ➔ Structural Interoperability to ensure that the data exchanged between systems can maintain its structure and therefore its meaning. This often involves having a common data model across participating systems.

- ➔ Process Interoperability so that systems have the ability to participate in and carry out business processes in a coordinated fashion, achieved through Business Process Management standards.
- ➔ Organizational Interoperability that involves agreements between organizations on how data is to be shared and interpreted in a broader business context. This often involves non-technical standards like MOUs or contracts → this interoperability should be developed for all **Policy Options** by setting up the top-level guidelines, management, and policies that enable the different stakeholders to collaborate and exchange data.

4. Data Models:
   - Develop data models to represent the structure and format of the exchanged information.
     - ➔ Gather requirements from key stakeholders to gain a full understanding of the application's data requirements, including system analysts, data engineers, users, and other interested parties, both at the National and Industry levels.
     - ➔ Conceptual Data Modeling: create a high-level view of the data structure that focuses on identifying entities (stakeholders), attributes (data used to produce DoCs), and relationships between these entities.
     - ➔ Create a logical data model to provide more detail, such as data types, primary and foreign keys, and entity relationships. Normalize data to minimize data redundancy and improve data integrity.
     - ➔ Physical Data Modeling: frame the logical data model to suit the technical requirements of the IT system. Implement the database system, including specifications for physical storage, indexing, partitioning, etc.
     - ➔ Create Database and Implement Model, with tables, keys, indexes, relationships, views, etc. Set permissions and security measures.
     - ➔ Load or migrate data from existing sources.
     - ➔ Perform rigorous testing to ensure the database can handle expected tasks in real-world conditions.
     - ➔ Regularly review and adjust the data model as needed, when new requirements arise, or current ones change.
   - Ensure compatibility with existing data standards.
     - ➔ Create a mapping of the existing data standards of the National and Industry databases to the new standards to identify any incompatibilities or potential issues.
     - ➔ Adopt universally accepted data standards that can fit all the Countries'/Industries' existing databases (standard data types, schemas, file formats, and protocols).
     - ➔ Ensure that the data types used in the new data model align with the existing data types. If existing and new data types are not compatible, define a valid and reliable conversion process.
     - ➔ Data Structure Compatibility: ensure consistency by reflecting in the new data model whether the existing data standards specify certain structures (such as XML or JSON).
     - ➔ Ensure that the definitions, constraints, and rules for maintaining data quality align with the existing standards. Data quality rules can include data validation, data cleaning, exceptions handling, etc.
     - ➔ Create metadata specifications that align with existing standards in terms of content, format and detail level. Metadata should be structured consistently across systems and follow a standard model to facilitate data discovery and interoperability. This will be critical as metadata will be used for the storage of files and traceability.
     - ➔ Define clear interfaces for data exchange between the new FCM System and existing National/Industry systems. Consider how the transition from the existing system to the new will occur, how the systems will interface during the transition, and how they will interface if they need to co-exist.
     - ➔ Once the data model is complete, test it against the existing standards to ensure compatibility during all potential use cases and workflows.
     - ➔ Review and update the data model to ensure continued compatibility as standards change and business needs evolve.

5. API Design:
    - Create well-defined Application Programming Interfaces (APIs) for communication between systems:
        - ➔ RESTful API (Representational State Transfer) uses simple HTTP methods, such as GET, POST, DELETE, and PUT, making them easy to understand and use → **most advisable choice** due to its scalability, statelessness, and platform independence, and its ability to handle multiple types of calls, return different data formats. Known for its robustness, versatility, and widespread adoption.
        - ➔ Web APIs: Also known as HTTP APIs or REST APIs, they allow communication between different systems over the internet. They utilize HTTP methods, and the data is often exchanged in JSON or XML format.
        - ➔ SOAP APIs: This is a standard protocol that uses XML for message exchange over networks. SOAP APIs can operate over any protocol, such as HTTP, SMTP, and more.
        - ➔ JSON-RPC and XML-RPC: These are remote procedure call (RPC) APIs that encode their data in either JSON or XML formats, allowing for data exchange between client and server.
        - ➔ GraphQL APIs: GraphQL allows clients to define the structure of the responses for more efficient data retrieval → this is good option to consider, as it enables the client to specify exactly what data it needs and helps in preventing over-fetching and under-fetching of data, thus reducing the amount of data transferred over the network and improving performance.
        - ➔ gRPC APIs: Developed by Google, gRPC APIs use Protobuf by default, enabling the definition of services in a much simpler way compared to REST and JSON APIs.
        - ➔ OData (Open Data Protocol) APIs: This API allows the client to query the server for specific data they need, offering more flexibility than simply accepting what the server returns.
        - ➔ WebSocket APIs: In contrast to HTTP-style APIs which are request/response-based, WebSocket APIs allow for a full two-way communication, keeping the connection open for real-time data transfer.
        - ➔ Library-based APIs: These are APIs offered by libraries in a specific programming language. They provide pre-defined classes, functions, and methods to perform various tasks without requiring the developer to write detailed code.

6. Authentication and Authorization:
    - Implement strong authentication mechanisms to verify the identity of users and systems.
    - Set up authorization controls to restrict access based on user roles and permissions.
    - Access Control: define roles for the system and assign access to the different stakeholders depending on their entities, and implement role-based access permissions, in accordance with the *Authorization & Access* and *Business logic* sections:

	PO1	PO2a	PO2b	PO3
Admin PO1: EU Body PO2a & b: MS/NCAs PO3: Industry consortium	**View & edit** unrestricted access to all the data			
NCA	**View & edit** unrestricted access to all the data			
Food business operator	**View** data about the FCM product used for their activity			
FCM Manufacturer and suppliers	**View & edit** data about their own FCM product			

    - The administrator and system should also incentivize users to adopt strong security protocols: secure password practices and multi-factor authentication relying on a password, a hardware token or mobile device and possibly biometric details (fingerprints or facial recognition). All authentication data, like passwords or biometric data, should be securely encrypted and stored.
    - Employees should be trained on the importance of encryption and secure practices to limit the risk of a user compromising the system.

7. Data Exchange Protocols:
    - Choose appropriate data exchange protocols, such as JSON, XML, or others, depending on the nature of the information:
        - ➔ HTTP/HTTPS: universally used for transmitting hypertext data → recommended given its high integration with REST, GraphQL, SOAP, or XML-RPC based APIs.
        - ➔ FTP/SFTP: File Transfer Protocol (FTP) and its secure version (SFTP) are standard protocols used for transferring files over Internet Protocol (IP) networks. They would be useful for the bulk exchange of data files between systems.
        - ➔ MQTT: Message Queuing Telemetry Transport (MQTT) is a lightweight protocol designed for limited bandwidth, high latency, or unreliable networks. It could be used for real-time tracking of food packaging in transit, particularly on Internet of Things (IoT) devices.
        - ➔ AMQP: Advanced Message Queuing Protocol (AMQP) is an open standard for passing business messages between applications or organizations. This protocol might come into play in scenarios where asynchronous communication is necessary.
        - ➔ SMTP: Simple Mail Transfer Protocol (SMTP) is a protocol for sending email messages between servers. It could be used to send automated notifications or alerts.
        - ➔ SOAP: SOAP is a protocol based on XML for exchanging structured information in web service communication. SOAP can function over any protocol, such as HTTP, SMTP, TCP, or others.
        - ➔ REST: An architectural style rather than a protocol itself, REST uses standard HTTP methods to read and write data, making it a straightforward choice for data exchange between services over the internet.

8. Message Queues and Middleware:
    - Implement message queues or middleware to facilitate asynchronous communication and handle high volumes of data, requiring the following steps:
    - Identify System Requirements and the nature of messages transmitted: since the system will track data such as FCM material composition, locations, processing, etc. the right speed, fault-tolerance, and scalability of messages must be set.
    - Choose a Middleware/Message Queue Service:
        - ➔ RabbitMQ: open-source message broker that supports multiple messaging protocols, known for its reliability, robustness, support of multiple messaging protocols and handling of high-throughput systems. It's also easy to set up and has a management interface that simplifies monitoring.
        - ➔ Apache Kafka: well-suited for real-time streaming and processing of data, high throughput, reliable and scalable in large systems. However, its setup and management can be complex.
          <u>Dependent on already existing ecosystem to be integrated with:</u>
        - ➔ Amazon SQS for its scalability and tight integration with AWS services
        - ➔ Google Cloud Pub/Sub: automatically scales to match the system's needs and integrates well with other services in the Google Cloud ecosystem.
    - Design Data Structures and Protocols to represent the information conveyed in a message, according to the chosen data format, and establish a protocol for how messages are structured.
    - Implement the message queue service according to the specific guides for the chosen platform: durable queues (that can survive a broker reboot), persistence of messages, and the logic for delivering confirmations.
    - Modify the relevant components of the system to produce and consume messages: "producers" (NCAs, FCM Supplier and Manufacturer) send or enqueue messages to the queue, "consumers" dequeue messages for processing (NCAs, Food Business operators). Both should handle potential errors (like network issues) and consider implementing a retry logic.

- Implement monitoring to ensure the health of the message queue and follow KPIs such as the number of unprocessed messages, message throughput, and processing delay.

9. Error Handling and Logging to ensure uninterrupted service and to maintain data integrity:
   - Develop robust error handling mechanisms to manage failures gracefully.
     - ➔ Input Validation: set-up data formats for every information and validate user inputs before processing, to avoid the processing of incorrect data, which could result in unforeseen issues.
     - ➔ Structure exception handling: 'try/catch/finally' blocks should catch errors that may occur during the execution so that it doesn't interrupt the entire system. In 'catch' blocks, that hold and handle the exceptions, suitable recovery logic, logging errors, or rethrowing errors, when necessary, should be implemented.
       By 'recovery', we mean that the system should enable a user to "undo" any erroneous entry that would cause an error and go back to the step before they inputted this data.
     - ➔ Use and define error codes and messages that clearly indicate what the error is about. They should be consistent across all the services of your system. For instance, send an error message in case the data inputted does not satisfy the fill-in criteria.
     - ➔ Use built-in error handling features provided by the system's programming language, frameworks, or third-party libraries.
   - Implement logging for tracking and analyzing system behavior.
     - ➔ Define logging levels like DEBUG, INFO, WARN, ERROR, and FATAL to filter logs based on their severity and control what level of logs should be captured in different environments.
     - ➔ Implement a centralized logging system that logs errors from all services in one place, making error checking easier (with tools like Logstash, Fluentd, or cloud services such as AWS CloudWatch).
     - ➔ Maintain a consistent log format that includes essential information like timestamps, error levels, error messages, and where it originated.
     - ➔ Use tools to monitor logs (such as Kibana, Splunk, and Grafana) and generate alerts based on specific error events or when errors exceed a certain threshold.

10. Testing:
    - Thorough testing of the system must be conducted to ensure its effective and reliable functioning, and must be done within a pre-production environment made available by the developers:
      - ➔ Unit Testing: Test individual units of software (functions or methods) to ensure that they work as expected, with frameworks such as JUnit (for Java), NUnit (.NET), or pytest (Python).
      - ➔ Integration Testing between different modules within the system to identify issues with data exchange, communication, or dependencies between various components of the system. **This will be especially critical to test the correct functioning of interoperability for PO2b and PO3.**
      - ➔ Functional Testing of the system, involving testing system features like tracking mechanism, data recording, reporting features, data accuracy, user interface, etc.
      - ➔ Performance Testing to evaluate the system performance under load, test the speed, response time, reliability, resource usage, etc. Tools like JMeter, LoadRunner, or Gatling can be used for these tests. **An emphasis must be put on stress testing to ensure that the system can handle peak loads, given the high expected throughput.**
      - ➔ Security Testing of the system's preparedness against threats, validating encryption practices, permissions, data access controls, etc.
      - ➔ Compatibility and Interoperability Testing across the different devices, browsers, and in-house operating systems of stakeholders, and with different software that it needs to interact with.

- ➔ User Acceptance Testing (UAT): in collaboration with future end-users of the system, representing a range of stakeholders, to assess if the system can handle real-world scenarios and meet all user needs.
- ➔ Regression Testing whenever modifications are made in the system to ensure that existing functionality is not broken due to the changes.
- ➔ Automated Testing for repetitive and large-scale testing scenarios. Tools like Selenium, Katalon Studio, or TestComplete can be used.
- ➔ Continuous Testing, as part of a Continuous Integration/Continuous Deployment (CI/CD) pipeline to ensure that all tests are automatically run at various stages of deployment.

Moreover, all test plans, test cases, and test results shall be documented for future reference and process transparency. Above all, a robust process for managing discovered defects must be set, involving the logging, prioritization, tracking, retesting, and validation of the fixes.

11. Deployment:
    - Deploy the information exchange system in a staged manner, ensuring minimal disruption to ongoing operations. This can be done in waves, either by country or by industry, depending on the Policy Option (cf. Implementation steps)
    - Decide on the system deployment strategy to follow, that will govern how the system is delivered into production:
        - ➔ Blue/Green Deployment: two environments, known as Blue and Green, are created. At any time, one of them is live. When a new version is to be deployed, it can be deployed to the idle environment, tested thoroughly and when ready, the traffic can be switched from Blue to Green or vice versa.
        - ➔ Canary Deployment: gradually roll out the change to a small subset of users before rolling it out to the entire infrastructure. Monitoring and validation can be performed to assess the stability and functionality of the new version before it's used by everyone ➔ **this strategy can be incremented by waves decided according to the Policy Option (PO2a & 2b deployed MS by MS, PO3 deployed Industry by Industry, PO1 can be done both ways).**
        - ➔ Rolling Deployment: with a phased rollout, the new system is progressively deployed to all instances, which enables to have zero downtime while allowing rollback if something goes wrong.
        - ➔ A/B Testing Deployment: multiple versions (version A and B) are deployed, and a portion of users are directed to each. This allows for performance comparison and selection of the best-performing version ➔ **as for Canary deployment, this strategy can be incremented with the versions tests by different MS/Industry depending on the Policy Option.**
    - Monitor system performance and address any issues that arise during deployment.
    - Use Infrastructure as Code (IaC) tools like Terraform, Chef, or Ansible to automate and manage the system's infrastructure.
    - Consider containerization for better deployment management and scalability, using Docker, Kubernetes, or any similar technology.
    - Prepare the hardware and software for deployment and set up appropriate server monitoring tools.
    - Sync the IT System with the various stakeholders' existing systems and the proper syncing and compatibility during the deployment process.

12. Documentation:
    - Gradually produce the necessary system documentation, that will serve as a roadmap for the system, and will assist in troubleshooting, system enhancements, training new team members, comply with audit requirements, and ensure overall system maintainability.
        - ➔ System Requirements Document that details the software and hardware requirements of the new system.
        - ➔ Technical Architecture Documents that outline the system's overall structure, including a detailed description of the components (data platforms, servers...) and how they interact (Hub for PO1 and PO2a, interoperability for PO2b and PO3).

- ➔ Deployment Plan that details the steps necessary for deployment, the technical requirements, the timeline, the potential risks, and their mitigations. Should also establish rollback procedures in case of deployment failure.
- ➔ Documentation of the API methods, request/response examples, and any error statuses and their meaning.
- ➔ User Manual with step-by-step instructions on how to use the system from a user's perspective as well as Frequently Asked Questions (FAQs) section. This manual should be user-friendly and adapted for each user category (FCM Supplier and Manufacturer, NCA, Food business operator, Admin), with different content and concrete examples on how to best use the system. They can include slide decks, videos, and/or interactive tutorials.
- ➔ Test Reports that document the result of all tests performed on the system, including unit tests, integration tests, system tests, load and stress tests, etc.
- ➔ Security Documentation with details about the system's security protocols, permissions, and privacy measures, as well as any relevant certifications or attestations.
- ➔ Release Notes and Change Log to inform users and system operators about any changes in upcoming versions of the software, including new features, bug fixes, and known issues.

13. Training and Support:
    - Provide training for users and administrators on how to use and maintain the system, that could include manuals, video tutorials, e-learning modules, or training workshops.
        - ➔ User Training: Develop training materials and programs that focus on how end-users can navigate and utilize the new system effectively.
        - ➔ Administrator Training for IT personnel or system administrators, who will need detailed technical training around system configuration, management, maintenance, and troubleshooting.
        - ➔ Continuous Training as system updates are rolled out, to ensure staff stays updated on how to leverage new features and enhancements.
    - Establish a support system to address user queries and issues.
        - ➔ System Support that users can contact for any assistance or to report issues. This could involve a dedicated helpdesk, email support, chatbots, or even self-service portals with FAQs and knowledge bases.
        - ➔ Technical Support, with a dedicated team ready to provide technical support and handle system maintenance tasks such as performing backups, security updates, troubleshooting technical issues, etc.
    - Implement change management to ensure the onboarding of the different stakeholders:
        - ➔ Develop a formal plan to help the stakeholders transition from the old systems and practices to the new one, with communication strategies, training plans, and user support mechanisms.
        - ➔ Regularly communicate with all stakeholders about the upcoming changes, including the benefits and any potential disruption. Keeping stakeholders informed can help ensure a smoother transition and buy-in.
        - ➔ Identify "champions" in all the stakeholder entities involved in the system (all the Member States and Industries): users who display an aptitude for the system's usage and will help to promote it and offer support to their colleagues. They will need to be identified clearly in all entities receive early in-depth training to have all the information needed during the projects roll-out phase and be reference points for the rest of the users.
        - ➔ Get users involved in system testing or provide them with early access to the system, in order to promote a quicker adaptation to the changes and to gather useful feedback.
        - ➔ Establish a feedback loop so users can report issues, suggest improvements, or voice concerns, and use this feedback to continually improve the system and its implementation.
        - ➔ Create a process for handling change requests after the system has been deployed. This could involve a review and approval process, prioritization of

changes, and a mechanism to roll out changes without disrupting the system's operation.

14. Continuous Improvement will enable to streamline the FCM IT system's processes and enhance its effectiveness over the long run, by improving efficiency, reducing waste, and increasing productivity.
    - Establish mechanisms for continuous improvement based on user feedback and evolving requirements.
    - Regularly update the system to address security vulnerabilities and introduce new features.
        - ➔ Use metrics, user feedback, manual reviews, and automated tools to identify areas of improvement: problematic areas of the system or inefficiencies in the deployment process.
        - ➔ Define clear and achievable improvement goals based on identified issues (for instance: reduce the system's error rates, increase deployment frequency, or enhance user satisfaction).
        - ➔ Implement improvements in a controlled and manageable manner, such as introducing new tools, modifying processes, refining code, or enhancing system infrastructure.
        - ➔ Implement robust Automated Testing such that every change should pass through comprehensive unit tests, integration tests, and system tests to ensure it meets quality standards.
        - ➔ Closely monitor the system after each improvement to assess its impact, using application performance monitoring tools to gain detailed insights.
        - ➔ Regularly review the changes and their impacts. Gather feedback from users and stakeholders to understand how the changes are affecting them.
        - ➔ Implement Continuous Integration / Continuous Deployment (CI/CD) pipelines using tools like Jenkins, CircleCI, or GitLab CI for regular, incremental updates to your system. This enables ongoing improvement without causing disruption. This will allow developers to integrate their changes back to the main branch as often as possible and allows deployment to production in a fully automated way.
        - ➔ Continuously gather feedback from all stakeholders, including end-users, developers, administrators, and management and use it to understand what improvements are necessary over time.
        - ➔ Keep the development and operations team up to date with training on the latest technologies, tools, and best practices to ensure they can contribute effectively to the ongoing improvement of the system.

15. Compliance and Governance:
    - Ensure compliance with relevant industry regulations and standards.
    - Implement governance mechanisms to monitor and enforce policies.
        - ➔ Implement a Compliance Management System to automate and manage compliance across the large number of EU member states and industries and ensure that all regulatory requirements are met continuously.
        - ➔ Make sure that the data protection measures respect the GDPR.
        - ➔ Conduct regular audits to ensure that the system is compliant with all the necessary regulations. This includes internal audits as well as third-party audits by external certified bodies.
        - ➔ Develop and document all policies and procedures for compliance. This should be communicated across all teams involved in the project.
        - ➔ Implement controls to protect sensitive information from being misused by employees, partners, or contractors (insider information). This can be done through restricted access and viewing rights, regular monitoring, and employee training.
        - ➔ Make sure that everyone involved in the project participates in training programs that explain regulatory requirements, company policies, and procedures, to reduce the risk of non-compliance due to ignorance of regulations.
        - ➔ Establish processes to promptly report, manage, and mitigate any compliance-related incidents.

16. Implementing a comprehensive system for monitoring and analyzing the FCM IT System's deployment to ensure it is operating efficiently and to identify areas for potential improvement:
    - Use analytics to gain insights into user behavior and system usage.
        - ➔ Determine the key performance indicators (KPIs) that are important for the system, like load time, response time, error rates, downtime, system utilization, success rates of deployments, etc.
        - ➔ Implement system and network monitoring tools to continuously oversee the system's performance, identify any abnormalities, and trigger alerts when issues arise (i.e. Nagios, Zabbix, or SolarWinds).
        - ➔ Enable comprehensive logging in the system and consider implementing a log management solution which can gather, analyze, and visualize log data in real-time (i.e. Logstash, Kibana, and Elasticsearch)
        - ➔ Application Performance Monitoring (APM) tools like New Relic, AppDynamics, or Dynatrace to monitor and manage the performance and availability of software applications.
        - ➔ Implement User Behavior Analysis tools to get insights into how users are interacting with the system.
        - ➔ Regularly monitor the data platforms for any performance or security issues (i.e. SolarWinds Database Performance Analyzer, Redgate SQL Monitor).
        - ➔ Security Monitoring wit Security Information and Event Management (SIEM) software, such as Splunk or IBM QRadar, for real-time analysis of security alerts.
        - ➔ Conduct regular reviews of the monitoring and analysis data to identify pain points, trends, opportunities for improvement, etc. Necessary adjustments should be made to the system based on these findings.
        - ➔ Set up a notification system to immediately inform the admin team members about significant events, issues, or anomalies detected by the monitoring tools.
        - ➔ Provide a performance dashboard giving a comprehensive view of the different monitoring metrics in real time.

17. Scalability: The FCM IT System should incorporate scalability by design, given the complexity of the FCM market and its multitude of stakeholders: the system should be able to adapt without major changes to the presentation or data access layers as the business logic evolves or the application load increase
    - Design the system with scalability in mind to accommodate growing data volumes and user loads:
        - ➔ **For Policy Option 1 and 2a**: design the system using microservices architecture. This way, each component of the system can be scaled independently based on demand, making the system more flexible and easier to manage. Since Policy Options 2b and 3 will rely on interpretability, each independent component of the system will be more easily scalable.
        - ➔ Use database systems that support sharding, indexing, partitioning, and replication. These capabilities will allow the databases to handle increased demand.
        - ➔ **For Policy Options 1 and 2a**: implement load balancing solutions to distribute network traffic across several servers, preventing any single server from becoming a bottleneck and ensuring reliability and redundancy.
        - ➔ Incorporate auto-scaling features that automatically scale the system up or down based on CPU utilization, or other defined metrics.
        - ➔ Employ caching techniques to temporarily store copies of data that's expensive to fetch or compute, to reduce the load on the databases and speeds up data retrieval times.
        - ➔ Content Delivery Networks (CDN) can be used to cache data closer to end users, which reduces latency and offers an enhanced user experience regardless of geographic location. This will be especially relevant for PO1.

18. Backup and Recovery: The system should be secured from any loss and to ensure business continuity, this is particularly the case for Policy Option 1 since it implies the use of a unique database. Back-up servers will continuously create a copy of data at regular intervals, making it possible to restore data in case of a data loss incident occurring due to system failure, cyber-attacks, or human error. Implementation can be done as such:
    - Implement regular backup procedures to safeguard data.
    - Develop a robust recovery plan in case of system failures.
        - ➔ Identify Critical Systems and Data that must be prioritized for backup.
        - ➔ Decide what type of backup is needed: Full backup, Incremental backup, or Differential backup.
        - ➔ Determine the frequency of backups needed (hourly, daily, or weekly, etc.)
        - ➔ Choose method of storage: for PO1 and PO2a, it should be in a different physical server than the main system. For PO2b and PO3, the different Member States/Industry Consortiums should each have a dedicated and separate back-up for their own data.
        - ➔ Encrypt backups to protect them from unauthorized access.
        - ➔ Regularly monitor the backup processes and periodically verify that the backups are successful, and the data can be restored.
        - ➔ Create a detailed and tested disaster recovery plan that outlines the steps to recover critical systems and data in case of a system failure, data corruption, or other disasters.
        - ➔ Consider redundant systems in separate geographical locations, especially for mission-critical applications. This ensures operations can continue even if one location is impacted. This is especially relevant for PO2 and PO3, so that one compromised system should not provide access to the other systems.
        - ➔ Preserve multiple versions of the data to allow recovery from various points in time, which is potent if corruption or deletion is not discovered immediately.
        - ➔ Regularly test the recovery process to ensure the systems and data can be restored effectively and in a timely manner.
        - ➔ Use backup software to automate the backups, they can schedule backups, compress data, encrypt data, report errors, and even fully recover systems.

19. Operational maintenance
    - Monitoring protocols once the system is deployed online, to oversee system performance and utilization. This can include the establishment of a Network Operations Center (NOC) equipped with system health metric dashboards and real-time applications monitoring tools to quickly identify and address any potential issues.
    - Deployment and tracking of batches to ensure the system updates don't affect or interrupt the system's functionality. To manage this, a continuous delivery approach (cf. point 11) can be employed where every code change is built, tested, and then pushed to a non-production testing environment where automated and manual functional testing takes place. It is only then the validated batches are deployed to the live environment.
    - Error management (cf. point 10.) with the implementation of automated system checks to detect errors, which can then be categorized and assigned to relevant teams for resolution. Also, by investing in sophisticated error logging and performance monitoring tools, traceability of errors or bugs back to their source can be carried out faster, leading to lower downtime.
    - Status reports relating to system usage, uptime, performance against service level objectives, errors identified and resolved, scheduled updates or improvements, and ongoing risk factors. This will ensure a level of transparency between the system’s administrator and the stakeholders relying on it and will facilitate Change Management during the deployment (cf. point 17.)

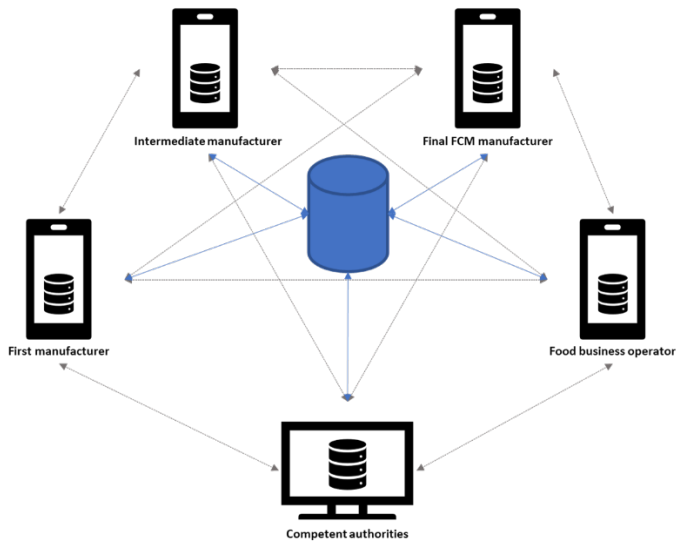
3 Other studied technologies

3.1. Peer-to-peer mobile system based on barcode for identifying products

Nowadays, data is the essential ingredient in any type of production to connect participants across the FCM chain to mitigate information asymmetry. The P2P technology is a powerful tool and emerging topic in recent food traceability research. P2P systems inherently have high scalability, robustness, and fault tolerance because there is no centralized server, and the network self-organizes itself. It has the characteristics of high throughput, low latency, powerful query functionality, decentralized control, immutable data storage, and built-in asset support. All of which has the high potential and usability to tackle the complexity of traceability within diverse supply chain. Blockchain is known as a common technology base on P2P network. Although it has some benefits and applications in finance, cryptocurrency and some agrifood supply chains, it still faces some limitations when it comes to implementation such as accessibility for resource-poor enterprises, the high energy consuming due consensus mechanism, inefficient storage and scalability obstacles, which remain problem in adopting traceability. A study conducted by researchers and data engineers (Kaiyuan Lin, David Chavalarias, Maziyar Panahi, Tsaiching Yeh, Kazuhiro Takimoto) and published in Nature Food in 2020 explains how a mobile based traceability system could work for food supply networks. Even if the food supply chain has its own specificities, the design of the IT system implemented can be taken up and analysed for use in food contact materials.

3.1.1 Design of the system

The mobility-based P2P traceability system deals with a set of systems for data collection, exchange, and storage systems with user-friendly, decentralized operational that can be applied to different modes of production and distribution. By enabling wider and easier implementation of "accurate and complete traceability", this system supports the management of diversified producers of different scales who are relatively disadvantaged but more sustainable, thereby contributing to balancing information asymmetry in the supply chain.



Mobile P2P system (mesh structure) with personal devices as database server

The system is designed for transparency and the mesh structure of communication for the food supply network is created, which enables individuals to coordinate and interlock supply chains to produce or service collectively. The decentralized nature of P2P networks allows actors in a supply chain to share surplus computing and storage resources on their personal devices with the entire network as peers.

3.1.2 Information integration in the system

The integration of information concatenation with mobile-based P2P network is coupled to a graph database[6], for high versatility and a user-friendly approach that implements an ideally mesh structure over stakeholders' communication and

[6] Graph database: graph database is the preferred structured of databases because it can easily

trace and track the end-to-end information of a specific point. It offers infinite scalability which plays a crucial role in the architecture on top of a decentralized network. The graph database offers operations which are more performant due to the required data-flow in our

information. This low-cost self-management tool for multi-scale holders is expected to further reinforce the food supply network with mesh surveillance and information symmetry while lowering entry barriers to the precise and complete traceability. The IT system will then be able to benefit from enriched, reliable databases that have been built in conjunction with all the stakeholders involved.

The building blocks of the mesh structure for food supply chain is a process of information concatenation that describes each newly generated piece of information in the database and inherits the full line of (or lineage of) associated upstream information. The 2D barcode is proposed as a common language for product identification in the system, to both carry and transfer the information as well as act as the media to access the information. It is commonly used in tracking and tracing initiatives because they are flexible in size, offer high fault tolerance and have fast readability, which can be read by any mobile device. QR codes, which are easy to generate, can also be used as an alternative. Not only is basic traceability information recorded, but users can also add any additional information to the database, which keeps the flexibility in addressing the diversity of products, production scales, and regulations. Stakeholders should first be registered and be given an ID. As long as the registered ID holders receive the product from others, they are interlinked. Through the mechanism of information concatenation, the transaction process of the product generates the new route of its barcode with the responsible IDs, which also allows the upstream information to be inherited to the next barcode. The traceability in the supply chain is therefore achieved without additional constraints, information is intuitively collected, which also reduces the workload in data collection, and the chain continues as long as the product keeps transacting to the next party.

3.1.3 System operations and user scenario

Each user in the supply chain must first register with the system. Validation is carried out by the designated regulator (depending on the policy option chosen, this may be a national authority, a European body, or a delegated body). The user is then assigned a unique identifier. This identifier is used not only to log in, but also to verify responsibility for modifications to the system. Clear record of responsible party in traceability among the supply chain contributes to the more precise recall and management, therefore, the ID registration in the system is mandatory to join the supply chain.

Every time the product is physically or chemically changed, the responsible ID holder should generate a new barcode. If the product has associated ingredients or components that the producer is utilizing or adding to modify the product, the producer is required to scan all their barcodes prior to generating the new barcode. The scanning action realizes the information concatenation to ensure the accuracy of traceability. Later, the product information or associated documents, such as the new declaration of compliance to generate the new barcode, must be inputted. After registration and authorization, each system user logs in via two-factor authentication. There are 2 types of authorization: manufacturer profile and competent authority profile. The manufacturer profile gives access to direct supplier DoC's only (no supporting information) and to customer transactions so that the manufacturer can know who has access to its information, control its confidentiality and maintain its data sovereignty. The competent authority profile gives access to all barcodes inherited by the final FCM barcode, to all compliance declarations and supporting information contained in these barcodes, and to all transactions in the chain.

Generation of the 1st barcode:

Step 1: the first manufacturer generates the new barcode, upload the declaration of compliance, add the supporting information and the database registers its ID.

Step 2: for the transaction, the sender (first manufacturer) scans the product barcode and a temporal 2D barcode appears for the transaction.

Step 3: the recipient (intermediate manufacturer) then scans this 2D time barcode and completes the transaction, which corresponds to the receiving process.

At this stage, the intermediate manufacturer will have access to the DoC through the barcode but not the supporting information because it is restricted to competent authority's profile.

Generation of the 2nd barcode

Step 4: If the product is chemically or physically modified, or combined with other products, the intermediate manufacturer must generate a new barcode. To generate the new barcode, the intermediate manufacturer must scan all the barcodes of the product's components and concatenate them into the new barcode. This also includes the compliance declarations of all components, to which the intermediate manufacturer adds the DoC and supporting information of his final product.

system, which makes them perfect candidates to be used in smaller devices such as phones, on a slow network connection, and a real-time architecture

Steps 5 and 6: for the transaction, steps 2 and 3 are repeated between the intermediate manufacturer and the manufacturer of the final FCM.

Generation of the 3rd barcode

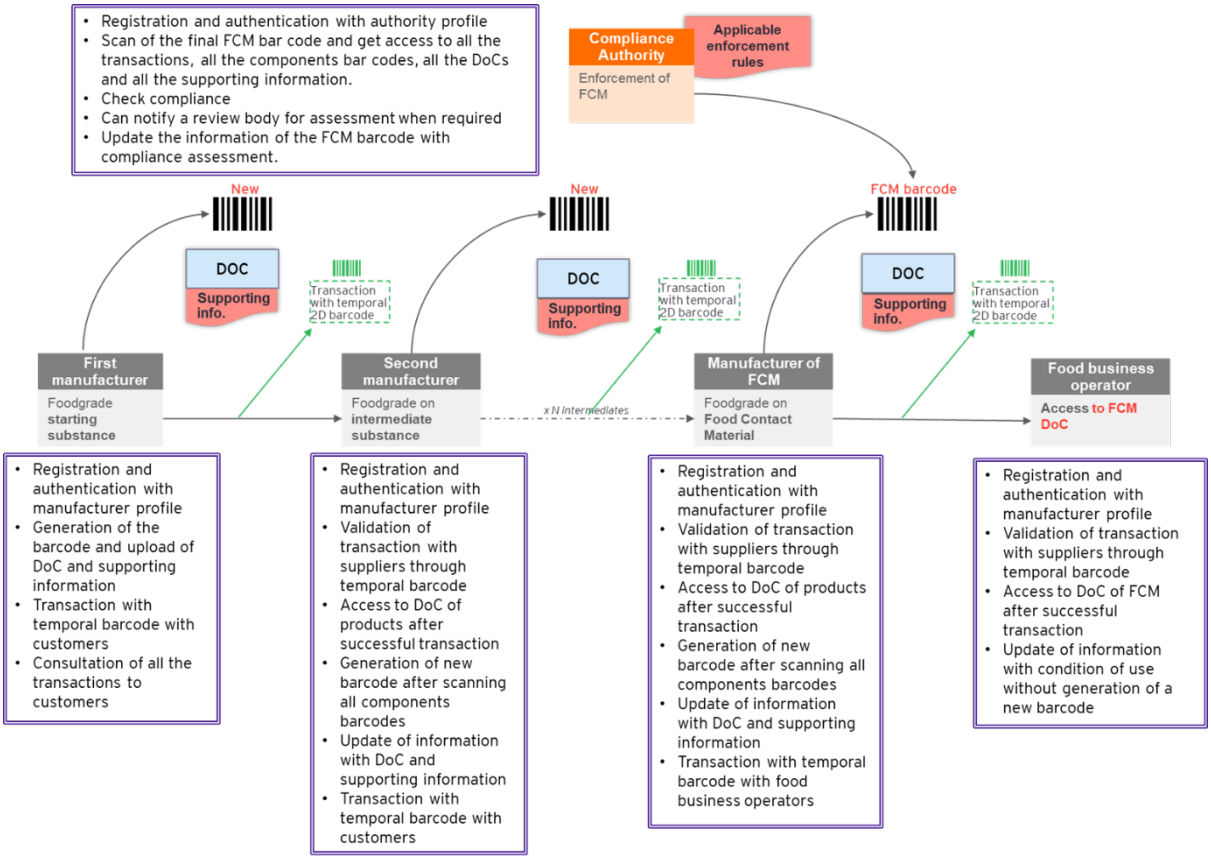
Step 7: The FCM manufacturer repeats step 5 and generates the last barcode, which will be the final product barcode sent to the food business operators.

Step 8: Steps 2 and 3 are repeated between the FCM manufacturer and the food business operator.

Step 9: The food business operator scans the barcode on his FCM and adds the conditions of use for foods in contact with the material.

Step 10: Competent authorities can log in with the authority profile, scan the final FCM bar code and thus get access to all the transactions, all the components bar codes, all the DoCs and all the supporting information.

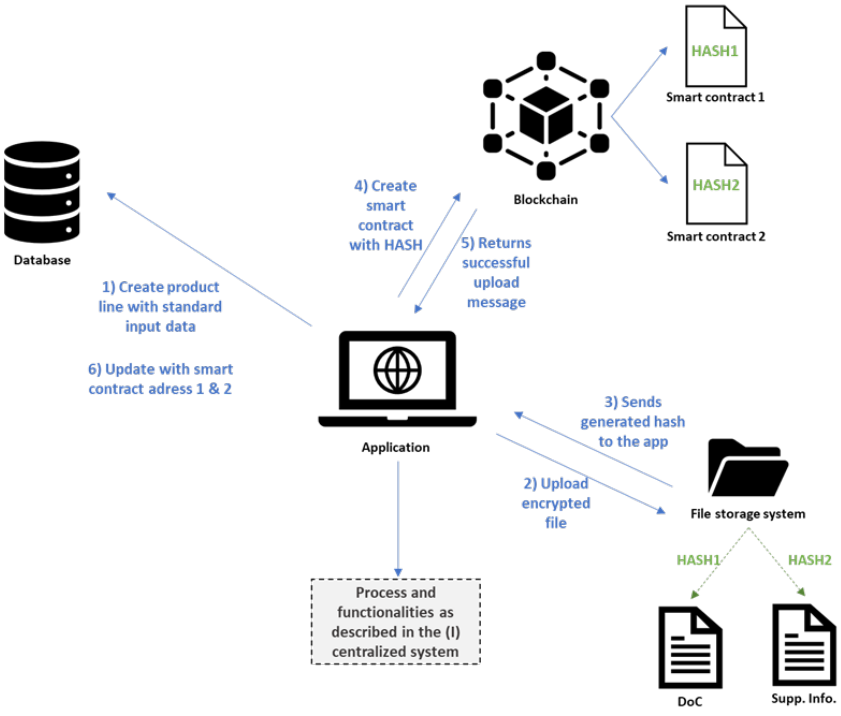
The diagram below shows the process of information exchange and compliance as described above:



3.2. Blockchain based system

3.2.1. Design of the system

The decentralized blockchain-based system should contain a decentralized application for user registration and authentication (manufacturers, authorities etc.), a centralized file storage system (could be included in a database) or distributed file storage system (e.g., IFPS) and finally a European blockchain: EBSI (European Blockchain Services Infrastructure). The application features a user interface, enabling manufacturers to register and authenticate themselves. The manufacturer also enters each of their products into the application, indicating the suppliers of the various components. For each product, the manufacturer must upload the declaration of compliance and supporting information, which will be stored by the application in the chosen storage system. In the frontend and functionalities, the application just works as the (I) centralized system based on a platform. Same processes are applied for manufacturers and competent authorities. The differences stand in the backend treatments.



Back-end application using blockchain for information exchange in the FCM supply chain

3.2.2. Information integration

The use of a database is also required: products' standard information, information regarding the supplier and smart contracts address related to the product are stored in the database. Smart contracts enable automated execution of agreements. Their address is a unique identifier on a blockchain generated when the smart contract is deployed which allows to locate it in the system and interact with it.

Smart contracts for each upload of documents: one smart contract is deployed when the DoC is uploaded in the application and one other smart contract is deployed when the supporting information are uploaded. In the smart contracts, metadata of the document is stored. The metadata is generated by the storage protocol system and will also serve to download the document from the file storage system.

3.2.3. System operations and user scenario

The process along the supply chain is the same as the one schematized in the (I) centralized platform system, only the operations performed by the backend system are different. Registration and authentication process happen just as in the (I) centralized platform system. The difference with this option is that registration on the application requires each user to create a wallet to identify the issuer on the EBSI blockchain. The first manufacturer registers their substances in the platform with standard information inputs and upload of DoC and supporting information. The intermediate manufacturer registers their product with standard data and input the components using the database (the database will add the smart contract addresses of all DoCs and supporting information of components in the product information)☐. The intermediate manufacturer sends a request to their supplier for access to DoC and/or supporting information of each component. In case of need of an NDA, the intermediate manufacturer proceeds to electronic signature. The supplier accepts access to the DoC (and supporting information if applicable)☐. The manufacturer can download the documents ☐and upload the new DoC of the product, as well as the new supporting information (database will add the new smart contract address to the data of the product). The final FCM manufacturer register their product the same way as the intermediate manufacturer does. Competent authorities can view all the databases with suppliers / products / and related documents by searching the final FCM in the database. This will be sufficient to retrieve all smart contract addresses from all DoCs for download from the file storage system.

3.2.4. Added value compared to the centralized application.

The use of blockchain instead of a conventional centralized system has different advantages:

- Tamper-proof Environment: Data provenance record is collected and then published to the blockchain network which protects the provenance records.
- End to End traceability: Users can access the provenance data to know the owner of the file, number of people who viewed the file and the edit operations on the file. Thus, no ownership problem occurs.
- Decentralization: blockchain operates on a decentralized network of nodes, which means there is no single point of control or failure. This reduces the risk of data breaches and hacking attempts since there's no central repository for attackers to target.
- Immutability: once data is recorded on the blockchain, it cannot be altered or deleted without the consensus of the network. This immutability ensures the integrity of confidential information.
- Permissioned blockchains: the European blockchain system infrastructure is a permissioned/private blockchain, limiting access to a select group. This enhances privacy while retaining the security benefits of blockchain.

The application as described provides with complementary advantages:

- Provenance Data Validation: Data provenance record is published globally on the blockchain network. Thus, provenance data is validated by the blockchain nodes
- No duplication of shared files: As any shared file may it be in public or private mode can only be decrypted using the application it cannot be downloaded in any end users operating system. Thus, no copies of the file exist.
- Real time data provenance: The audit logs obtained include user information and the operations performed on the file may it be view is then added to the blockchain network making it tamper-proof.

However, the blockchain technology comes with several limitations that could be detrimental to our use cases especially regarding low scalability, regulatory challenges, cost, and complexity, onboardings and training of users and energy consumption.

In summary, while blockchain offers several security and integrity advantages for exchanging confidential information, it's crucial to assess whether these benefits outweigh the drawbacks and whether blockchain aligns with the specific needs and regulatory requirements.

3.3. Conclusions on these technologies

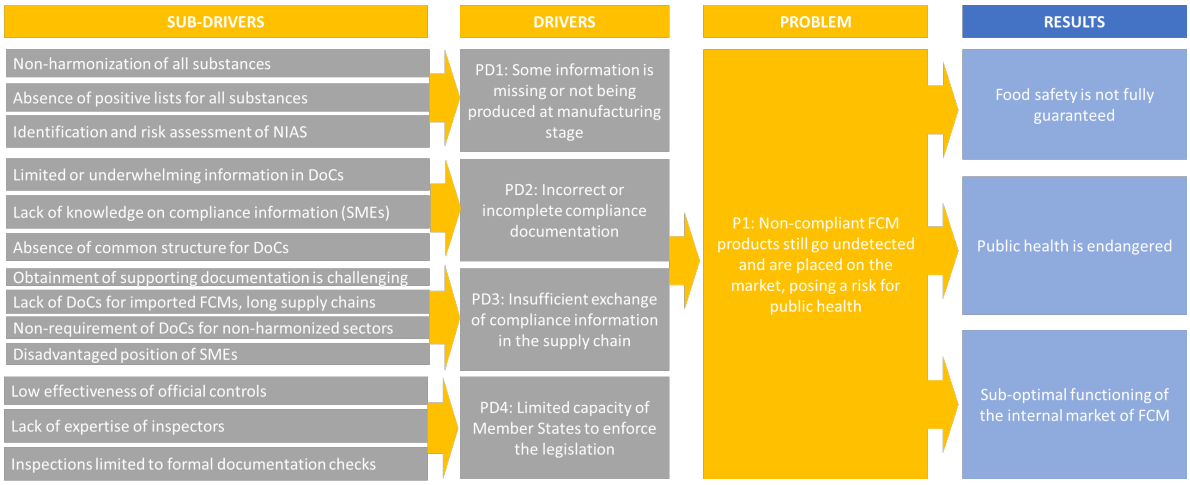
Features	Decentralized mobile-based technology	Blockchain Technology
Decentralized	Yes	Yes
Energy consumption	Low	High
Distributed computing system	Yes	No
Storage usage	Low	High
Scalability	Strong	Weak
Stable security	Yes	Yes (needs >50%)
Real-time	Yes	Several minutes depending on the EBSI blockchain
Offline	Yes	Not yet
Confidentiality	Medium	High
Data ownership	Medium	High
Tested technology	New (research purpose only)	Implemented in some areas but not yet tested on a significant scale

4 Problem definition

In this section, we seek to define the problem at hand in the framework of this impact assessment support study, in accordance with Tool #13 of the Better Regulation Guidelines. The verification of the existence of a problem and the actors that are affected by it, including the scale of the problem, its drivers and likelihood of persistence, are paramount to a successful identification of the appropriate policy responses. The following problem definition was validated as part of the Inception Report and was not made subject of further investigation during the consultation activities carried out under Task 2, which were aimed at defining the policy options, as agreed with the European Commission during the Inception meeting.

The paragraphs below present the definition of the problem and its drivers as validated in the Inception Report. Data from the evaluation, its supporting study, desk research and exploratory interviews were utilised.

Figure 1 Problem tree



Sources: EY analysis based on Terms of Reference background documentation and exploratory interviews

4.1. Problem 1: Non-compliant FCM products still go undetected and are placed on the market, posing a risk for public health

The experience gathered by enforcement authorities shows that there are still several cases in which substances possibly posing a risk to public health were not detected during compliance assessments on FCMs and may have hence migrated to food[7]. In all these cases, FCMs were compliant on paper but, upon inspections, they have been found to be far from safe in terms of the risk posed to public health. Some of these cases are presented below.

In 2012, when authorities requested documentation on the safety of cyclo-diBA, a cyclic compound formed from bisphenol A and BADGE, the industry was not able to provide data on its toxicity nor to reduce its migration to food[8]. Four years later, the situation had not changed, and a German enforcement laboratory still found the same level of migration, meaning that no measures had been taken in the meantime and the substance had continued to pose a risk to public health[9].

In 2013, after a series of cases of non-compliance of oily food for the excessive migration of plasticizers from the gaskets of lid for glass jars where they were packed, the enforcement authorities of Zurich and Stuttgart launched a campaign aimed at controlling documentation, in which 12 additional European

[7] Jürg Daniel, Karsten Hoetzer, Gregor McCombie & Koni Grob (2019) Conclusions from a Swiss official control of the safety assessment for food contact polyolefins through the compliance documentation of the producers, Food Additives & Contaminants: Part A, 36:1, 186-193

[8] Biedermann S, Zurfluh M, Grob K, Vedani A, Brüschweiler BJ. 2013. Migration of cyclo-diBA from coatings into canned food: method of analysis, concentration deter-mined in a survey and in silico hazard profiling. Food Chem Tox. 58:107–115.

[9] German Federal Institute for Risk Assessment (BfR). 2016.16. Sitzung der BfR Kommission für Bedarfsgegenstände.[Ergebnisprotokoll vom 2016 Apr. 6]

countries participated. The campaign revealed that reasonable compliance work had been performed for only 6 out of 48 products under assessment. In addition, in 29% of the samples analyzed, the migration limits were exceeded, meaning that such products could pose a potential threat to public health10. Research claims that 10 years after this campaign, no adequate measure to limit the migration of such substances had been taken11.

In 2014, a consortium of enforcement authorities in Switzerland – where the EU FCM legislation applies – assessed the compliance documentation for polyethylene and polypropylene granulates from nine major producers. Such polymers are used at early stages of the manufacturing chain, where solid compliance work should be performed to enable actors in subsequent stages of the chain to assess compliance. The assessment revealed that 7 of the 9 substances analyzed exceeded migration limits, highlighting a substantial gap between the legal requirements of the Regulation in terms of safety assessment and the compliance work submitted by suppliers12.

Research shows that there is a "large gap between the required safety assessment and the reality (e.g., McCombie et al. 2016; Grob 2017a; Daniel et al. 2019)". Accordingly, "hardly any FCM on the market meets the EFSA requirements for all migrants, […] due to the many not specifically regulated substances used and particularly the reaction products and impurities (e.g., Muncke et al. 2017)" 13.

According to the evaluation undertaken on the FCM Regulation, competent authorities experienced that, upon request, compliance documentation was often lacking or at least not readily available. This was due to several factors, including the lack of information at initial stages of the supply chain, confidentiality matters on the part of the industry, poor exchange of information among the actors in the supply chain, and low enforcement capacities on the part of Member States' authorities. In practice, this means that, on the one hand, the industry is not fully capable of proving compliance of their products and, on the other hand, that national competent authorities cannot verify whether FCMs are compliant with all legal requirements. In turn, this may lead to non-compliant FCMs still entering the market.

The problem driver affects not only the actors involved in the supply chain of FCM, as well as competent and enforcement authorities in Member States, but also the general public (i.e., consumers). The Regulation has generally improved the safety of FCM products in terms of public health, in particular for those harmonized substances for which positive lists exist; however, the problem persists, especially for non-harmonized substances.

4.2. Problem Driver 1: Some information is missing or not being produced at manufacturing stage

In the context of the evaluation, as well as during the consultations, it was found that industry does not normally have or is not able to produce all the information needed in-house to compile compliance documentation. According to a study by enforcement authorities[14], following a request of Member States, the chemical industry could not provide an adequate supporting documentation showing that they comply with the Regulation. A senior expert on FCM enforcement from Switzerland, interviewed in this inception task, pointed out that, in almost all inspections, in-house compliance data was simply not available and therefore the compliance documentation could not fully prove the safety of FCM.

The Regulation mandates that all business operators along the manufacturing chain record their compliance work in-house in compliance documentation, to be made available to competent control authorities upon request. Producers would normally list migrating substances, including substances used as well as reaction products and impurities and provide facts supporting the safety of such substances. The latter is usually proven by referring to an approved list of previously evaluated substances; however, only few migrating substances are listed as officially approved (roughly 1000 in the Plastics Regulation as well as in national

[10] McCombie G, Harling A, Biedermann M, Biedermann-Brem S, Eicher A, Suter G, Morandini M, Pechstein S, Schmäschke G, Lauber U, et al. 2015. Survey of plasticizers migrating from the gaskets of lids into oily food in glass jars: the second European enforcement campaign shows poor compliance work. Food Control. 50:65–71

[11] Jürg Daniel, Karsten Hoetzer, Gregor McCombie & Koni Grob (2019) Conclusions from a Swiss official control of the safety assessment for food contact polyolefins through the compliance documentation of the producers, Food Additives & Contaminants: Part A, 36:1, 186-193

[12] Ibid.

[13] Koni Grob (2019): The role of the European Food Safety Authority (EFSA) in a better European regulation of food contact materials – some proposals, Food Additives & Contaminants: Part A

[14] McCombie G, Hötzer K, Daniel J, Biedermann M, Eicher A,Grob K. 2016. Compliance work for polyolefins in food contact: results of an official control campaign. Food Control. 59:793–800.

lists). Non-listed substances, including reaction products and impurities, have to be assessed by the manufacturer "in accordance with internationally recognized scientific principles on risk assessment" (Article 19, Plastics Regulation). Nevertheless, it is seldom that such substances are assessed due to several factors, including the cost for the industry to perform such assessments, the lack of guidance and of sanctions.

A key case is that of NIAS ("non-intentionally added substances"). NIAS are impurities of the starting substances that formed as a reaction and degradation product during the manufacturing process. Their assessment by the industry is usually left out, although they constitute the majority of migrates. As confirmed during the kick-off meeting, no information on NIAS is currently transferred at supply-chain stages.

In the evaluation support study[15], the identification of NIAS was perceived as a major concern by all consulted stakeholders. In particular, almost 90% of the companies consulted during the evaluation reported that they were missing adequate information on NIAS. In principle, all actors in the chemical industry would need to communicate the full information on NIAS along the supply chain; however, most of the time the responsibility of compliance of the NIAS is transferred to the producer of the final product. This is problematic as it is difficult to perform a risk assessment at the end of the supply chain. In turn, this creates obstacles for ensuring compliance of the final FCM. In fact, the composition of the product might vary at each batch and the link between used chemicals and NIAS peaks are missing, as producers of final products are not aware of the chemical composition of their products. This has an impact downstream, as the lack of risk management information of NIAS in the DoCs will make it difficult for downstream users to perform their own risk assessments. The evaluation support study reports the case of azodicarbonamide (ADC), for which the discovery of one degradation product (semicarbazide) in 2004 by an enforcement laboratory was problematic as its origin was not known.

The evaluation support study found that assessing the potential toxicity of NIAS for compliance is also a challenge. In the 2012 case of the discovery of cyclo-diBA as a NIAS, the industry was not able to provide data on toxicity, nor to reduce the migration[16]. In the evaluation support study, consulted businesses were concerned about the lack of clear guidance from the European Commission on NIAS assessment. EFSA has provided recommendations on the assessment of NIAS; however, the latter remains a responsibility of the industry, which published recommendations and guidance documents addressing the evaluation of NIAS and hence produced a multitude of proposal and approaches. The lack of clear and comprehensive EU rules hinders therefore the adoption of a single approach on the assessment of NIAS. The issue is currently being discussed in the FIP network of EFSA, which could lead to harmonization.

4.3. Problem Driver 2: Incorrect or incomplete compliance documentation

The evaluation[17] found that the information contained in DoC is usually limited or underwhelming to ensure a proper assessment of compliance. Also, stakeholders expressed concern regarding the lack of sufficient quality criteria for both DoC and SD. The analysis performed during the evaluation showed that most DoCs contain only basic information and are limited to mentioning compliance with the FCM Regulation and the plastics Regulation. The public authorities involved in the evaluation support study reported that companies usually perceive compliance work as paperwork and therefore limit their effort to issuing documents, adding a report from a service lab with data on overall migration, information on a few authorized substances and the absence of some substances considered important by the customers. The senior FCM enforcement expert explained, during the exploratory interviews, that the base of "adequate information" would generally be missing in DoCs. The latter would present data gaps and actors in the supply chain would normally make use of complete disclaimers to waive responsibility.

The evaluation identified that the main shortcomings of DoCs concerned referencing rules on GMP, the clear identification of substances used, dual use additives, functional barriers and specifications on the adequate use. Few provided the identity of upstream suppliers, and many were incorrectly filled-in and incomplete. The EuPIA confirmed during the exploratory interviews that, for instance, ink manufactures experience difficulties obtaining disclosure of their raw material suppliers. The trade business associations involved in

[15] European Commission (2020), Study supporting the Evaluation of Food Contact Materials (FCM) legislation - (Regulation (EC) No 1935/2004)

[16] Jürg Daniel, Karsten Hoetzer, Gregor McCombie & Koni Grob (2019) Conclusions from a Swiss official control of the safety assessment for food contact polyolefins through the compliance documentation of the producers, Food Additives & Contaminants: Part A, 36:1, 186-193

[17] European Commission (2022), Commission Staff Working Document: Evaluation of the legislation on Food Contact Materials - Regulation (EC) No 1935/2004

the evaluation support study identified issues in the functioning of information in the supply chain, frequently mentioning the lack of a common structure for DoCs, lack of clarity of responsibilities and varying degrees of knowledge on FCMs along the supply chain. In addition, SMEs would lack awareness on compliance documentation and would tend to produce less qualitative compliance information.

During the exploratory interviews, a national NCA explained that, although the quality of the information provided in DoCs is generally improving, it is still sometimes insufficient. This would be due to a general lack of knowledge of business operators of the details of the template for compliance, as well as of what information to pass on to the customer – in particular for non-harmonized materials. This claim was seconded by another national NCA interviewed during this inception task. A representative from Foodchain ID explained that SMEs would generally accept materials with incomplete DoCs, passing the responsibility of missing information to the next actor in the supply chain.

The evaluation found that the experience of not receiving adequate or correct information led to a lack of trust among actors in the supply chain, which has further contributed to companies re-performing the compliance work performed by the manufacturers of starting substances.

4.4. Problem Driver 3: Insufficient exchange of compliance information in the supply chain

In the evaluation, the presence of documentation along the FCM supply chain, proving that materials and articles comply with the rules applicable to them (Article 16), was found to be insufficient.

Transferring information along the supply-chain is mandatory at EU level only for FCM covered by specific measures, as in the case of plastics. For instance, the evaluation highlighted how the plastics Regulation is supplemented by guidance documentation, including on information exchange in the supply chain and testing guidelines. In the evaluation support study, consulted stakeholders found this guidance essential to be able to fulfil their compliance work. The evaluation refers to a survey on DoC and SD undertaken by DG SANTE[18] in which 227 businesses, 59 trade and business associations and 230 public authorities participated, showing that the documentary system based on DoCs and SD has become common practice within the FCM sectors, with the use of DoCs even for FCMs for which there are no EU-specific measures.

The evaluation found that the obtainment of adequate supporting information through the whole supply chain is challenging. In fact, although businesses reported receiving DoCs from their supplier, supporting information was more difficult to obtain due to confidentiality issues and lack of knowledge, particularly among SMEs. In the evaluation, it is discussed how downstream users are better placed to estimate the likely consumer exposure to substances. Nevertheless, it is also indicated that such users would need to have access to the necessary information contained in confidential documentations supporting DoCs produced by the chemical industry, which is currently not transferred at supply-chain stages. The representative from Foodchain ID underlined the importance of having access to supporting documents for judging the quality of DoCs. According to Metal Packaging Europe (MPE), the confidentiality of the formulations of the materials that compose FCMs (e.g., coatings, sealants) is challenging. Suppliers (and even more so raw material suppliers) are reluctant to provide detailed compositional information, as they fear competition. As a consequence, the metal packaging industry manages compliance mainly using third party institutes who are able to get the full compositional information and do all required migration testing to demonstrate compliance. A study mentioned in the evaluation[19] envisaged that a mechanism that would relax the confidentiality of this supporting documentation could contribute to improved assessment of the compliance of the FCM put on the market by downstream FCM users. The matter of confidentiality is central for certain industries and actors in the supply chain. During the exploratory interviews, the EuPIA underlined the importance of confidentiality for ink manufactures when it comes to the recipe of their products. Accordingly, the industry finds that the information shared in DoC is already sufficient and transparent and that CBI needs to be observed.

The evaluation pointed out that also the obtainment of DoCs in the supply chain could not be given for granted. This is the case of DoC information for imported FCMs and for FCMs with long supply chains. The

[18] European Commission (2022), Study on compliance documentation on food contact materials (FCMs) in the supply chain.

[19] Koni Grob (2019): The role of the European Food Safety Authority (EFSA) in a better European regulation of food contact materials – some proposals, Food Additives & Contaminants: Part A

JRC Baseline report[20] noted that the longer the supply chain, the more difficult it is to ensure FCM compliance, especially in the case that the supply chain is not entirely composed by ISO 9000 certified companies. In addition, in supply chains that include non-EU countries, it becomes difficult to identify imported FCMs, for instance in the case of recalls or withdrawal from the market. This information was corroborated during the exploratory interviews by the representative of the German NCA, who informed us of a Swiss-German pilot project on compliance information and documentation throughout the FCM supply chain. Accordingly, the project registered the difficulty of competent authorities to judge that the compliance work had been done properly, as it was difficult to gather the needed information from different Member States or third countries. Both public authorities and business in the evaluation pointed out that ensuring the completeness and quality of DoCs from imported FCMs is challenging, as they both lack access to the previous segments of the supply chain. In fact, DoCs for such materials come from importers, who issue them based on the information they get from suppliers, without having a specific mandatory template to follow and usually experiencing difficulties when demanding further technical documentation. For these reasons, the information provided by importers is also difficult to verify.

SMEs experience difficulties demonstrating compliance, as their leverage to obtain complete DoCs or supporting information from suppliers is lower than that of larger companies. In this context, public authorities involved in the evaluation reported that there are often questions from SMEs on missing DoCs or SDs. Also, when seeking to get information from suppliers, collecting DoC from suppliers and updating the DoC when Regulation is changed, larger enterprises would normally outsource such activities; however, this is more difficult for SMEs due to the associated costs. The EuPIA confirmed during the exploratory interviews that small ink manufactures experience difficulties getting information from their suppliers.

In addition, the evaluation mentions the case of the non-requirement of DoC for non-harmonized sectors. Stakeholders (businesses, business associations, NGOs, and public authorities) generally agreed that the requirement for a DoC should cover all material types; however, as this was not the case in Regulation 1935/2004, the industry proceeded to self-regulation by recommending the use of DoC. This is not however legally binding. The evaluation registered misunderstandings and confusion among the actors in the supply chain, especially in the case of companies that are asked to provide DoC even for non-harmonized sectors in some countries (e.g., Denmark, Italy) whereas this is not the case in others.

During the exploratory interviews, the EuPIA outlined that, even in the case of intermediate materials, there are no specific measures. As a consequence, it is the actor placing the material on the market that needs to make sure it is safe. The printing ink industry, for instance, has arranged a solution to provide information on potentially migrating substances to the next actor in the supply chain. In particular, ink producers supply converters with a Statement of Composition (SoC) of the printing ink, which will list the substances that could potentially migrate along with applicable migration limits and the amount of that substance in the print.

The representative from Foodchain ID explained during the exploratory interview that the insufficient exchange of compliance information by suppliers would cause downstream users to face higher compliance costs, as they would not be able to perform compliance assessments based on worst case calculations and /or migration modelling, which are cheaper and more correct solutions to prove compliance but that require transfer of information.

4.5. Problem Driver 4: Limited capacity of Member States to enforce the legislation

The evaluation pointed out that capacity of Member States to enforce the legislation is limited. The system of Official Controls applies to all products, substances and materials that may come into contact with food and hence affect food safety. They are meant for competent authorities in Member States to examine the statements of compliance produced by business operators, their reliability, the results of businesses' own controls as well as GMP procedures. Non-compliance is then reported via the Rapid Alert System for Food and Feed (RASFF) or the Administrative Assistance and Cooperation (AAC) system.

The evaluation reported that, between 2007 and 2011, the Commission visited and audited 22 national control systems[21]. It was found that several Member States, mainly the ones who had recently joined the EU, had either just implemented a control system, needed assistance to further develop them in terms of specific guidelines, upgrading of laboratories and training, or had issues clarifying the competences for

[20] Joint Research Center (2016), Non-harmonized food contact materials in the EU: regulatory and market situation. Baseline study

[21] European Commission, audit reports https://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

official controls. As a consequence, the latter were generally lacking or overlapping. In 2017 and 2018, another round of audits confirmed that official controls on FCMs in Member States were generally weak, not effective and considered low priority[22].

The evaluation identified a key constraint to the effectiveness of the system of official controls, which is that controls are limited to formal documentation checks, particularly of the presence of DoCs, without a proper verification or assessment of the latter. According to the evaluation, inspectors in fact rarely have the expertise to verify their content, this was confirmed through exploratory interview undertaken. Furthermore, it has been identified that the system lacks a comprehensive checklist for compliance check, guidance documentation including for the evaluation of DoCs and that controls are poorly documented. In other cases, the presence of DoCs and SDs is not granted, as they are not required beyond specific materials. In the latter case, Member States and industry are free to define their own approach.

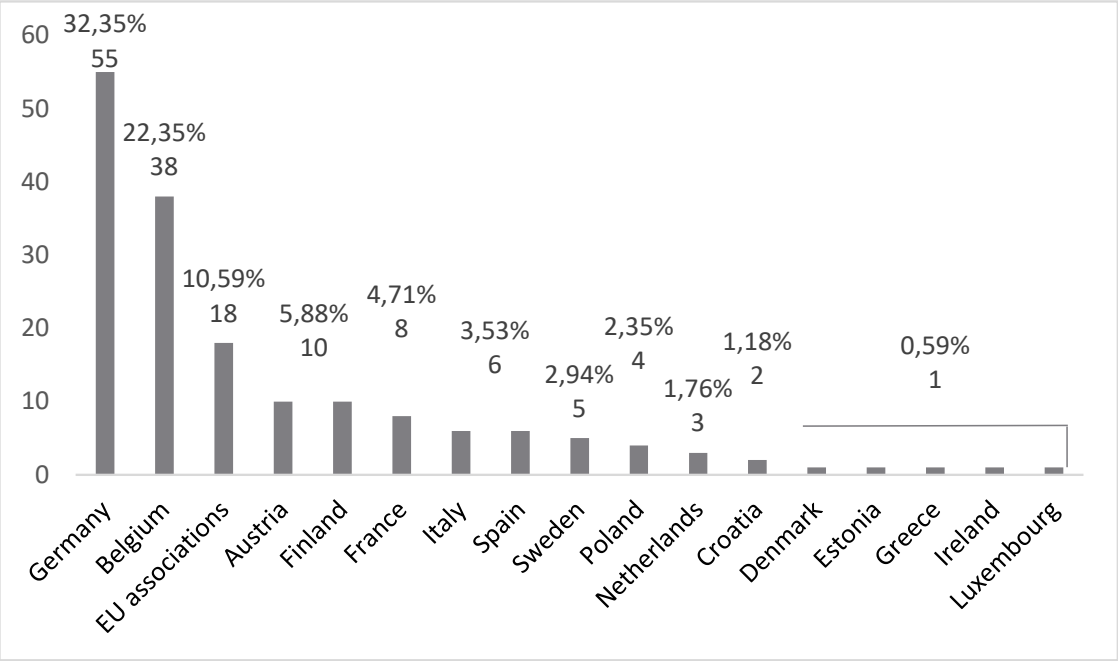
The representative of Foodchain ID claimed, during the exploratory interviews, that there would be almost no control on the content of DoCs, which would in turn cause that companies are not pressured to invest on improving their compliance assessments. The senior expert on FCM enforcement from Switzerland pointed out that the legislation cannot be fully enforced due to the lack of in-house compliance data that does not allow to prove that the information contained in DoCs is correct and, hence, that the FCM is safe.

5 Consultation activities

5.1. Online questionnaire

5.1.1 Introductory questions

Figure 2 Question 1. Please select your Member State (170 respondents)



[22] European Commission, audit reports https://ec.europa.eu/food/auditsanalysis/overview_reports/act_getPDF.cfm?PDF_ID=1732

Figure 3 Question 2. What kind of organization do you represent? (170 respondents)

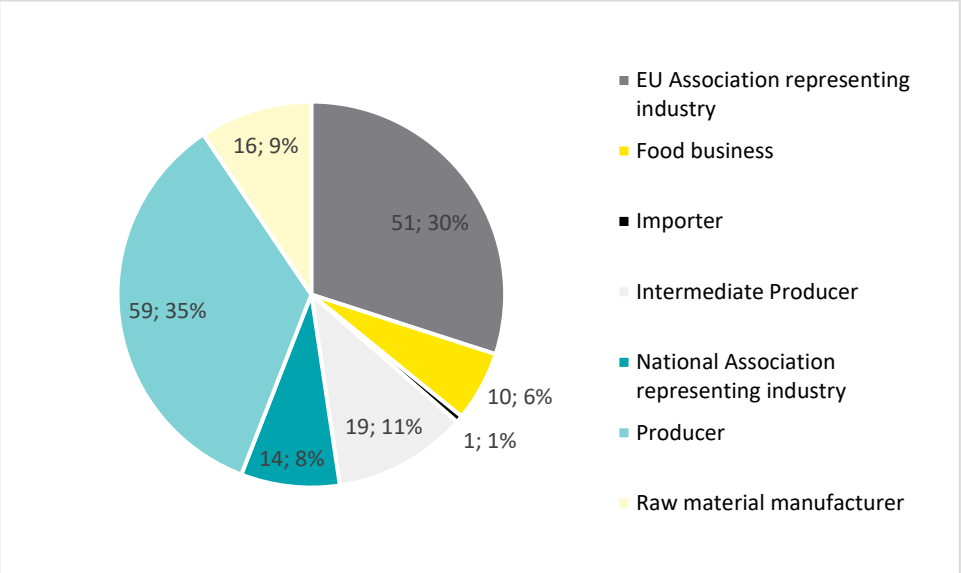


Figure 4 Question 4. Please indicate whether you represent industry/a business dealing with one or more of the following materials (159 respondents)

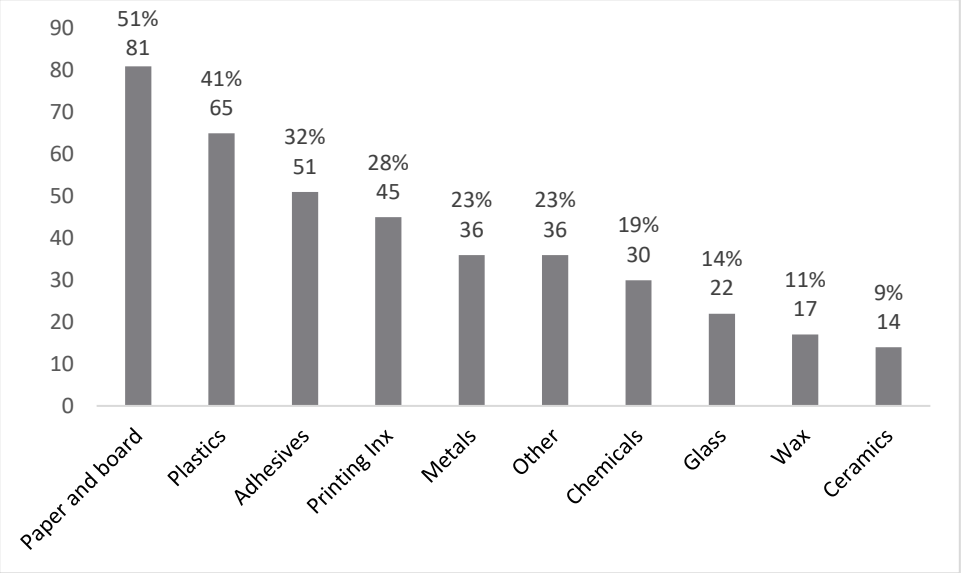


Figure 5 Question 5. Please indicate the number of employees in your business

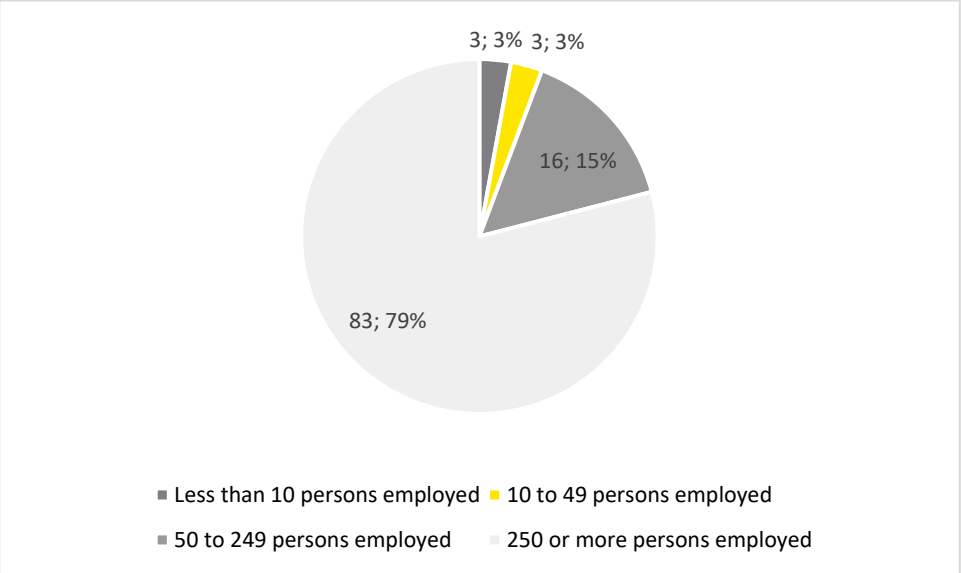


Figure 6 Question 6. In terms of full-time equivalent, (FTE), how many individuals are currently working on compliance in relation to Food Contact Materials within your business ? (105 respondents)

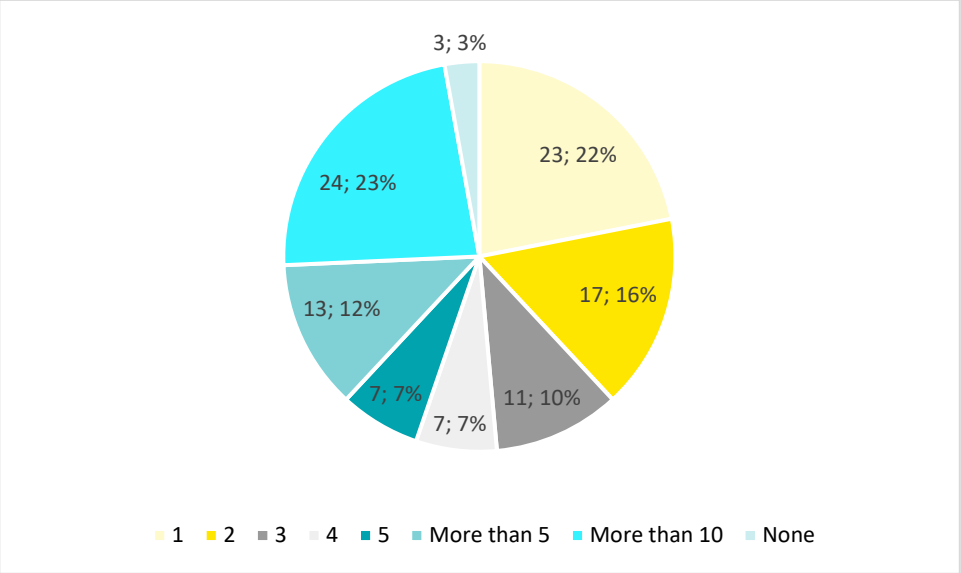


Figure 7 Question 7a. Please select the most appropriate rating for the following questions: - Overall, how would you assess your knowledge of EU rules relating to Food Contact Materials (harmonized substances)? (158 respondents)

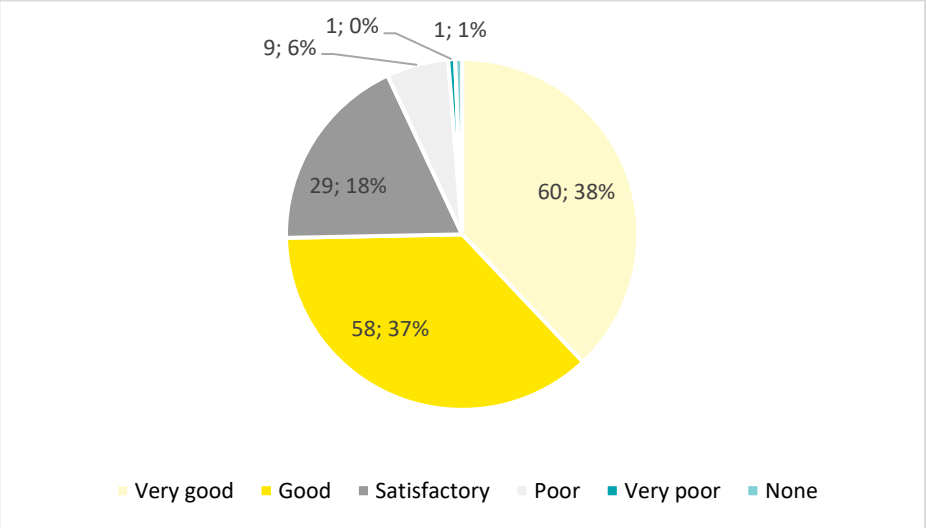
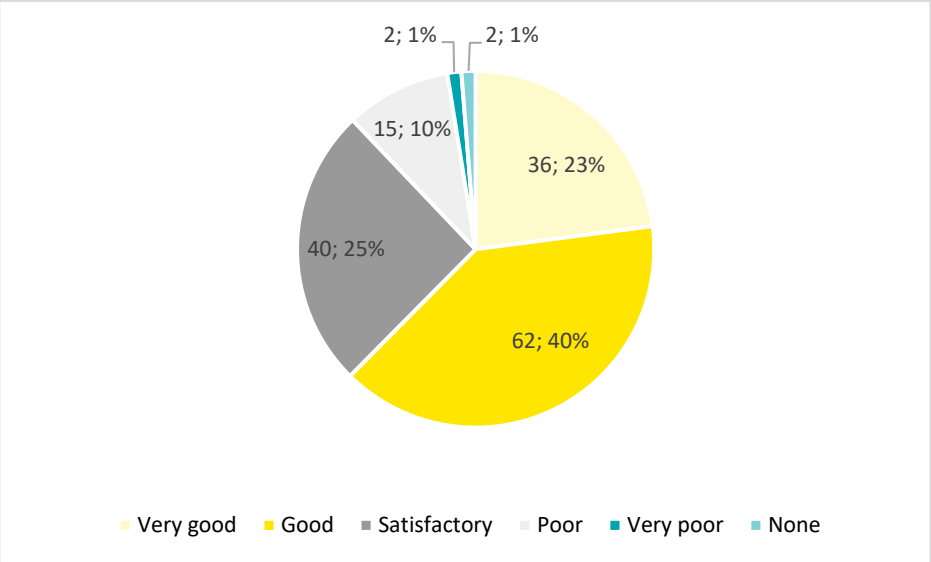


Figure 8 Question 7b. Please select the most appropriate rating for the following questions: - Overall, how would you assess your knowledge of national rules relating to Food Contact Materials (non-harmonized substances)? (157 respondents)



5.1.2 Current information exchange

Figure 9 Question 8. In relation to information exchange for harmonized substances, to what extent do you agree with the following statements: (137 respondents)

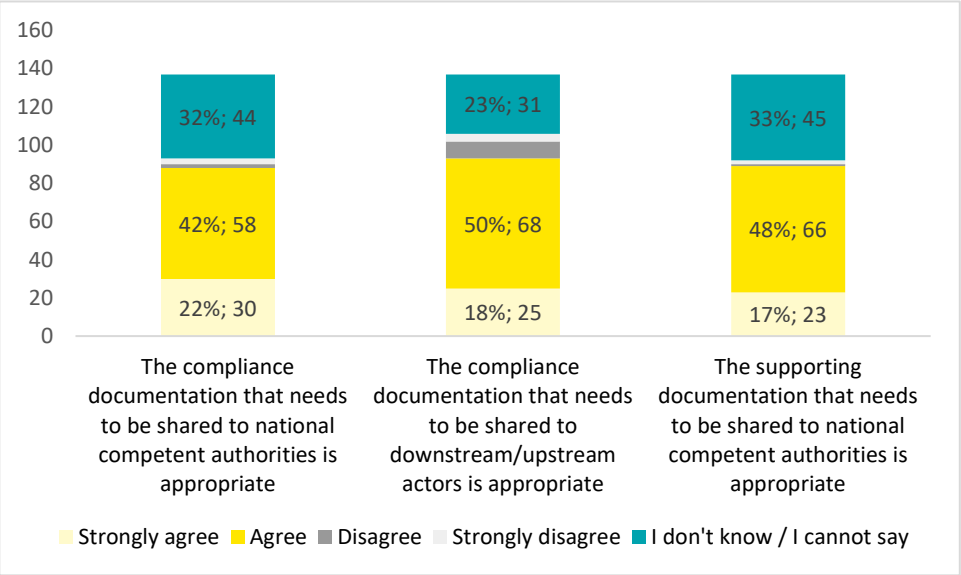


Figure 10 Question 9. In relation to information exchange for non-harmonized substances, to what extent do you agree with the following statements: (137 respondents)

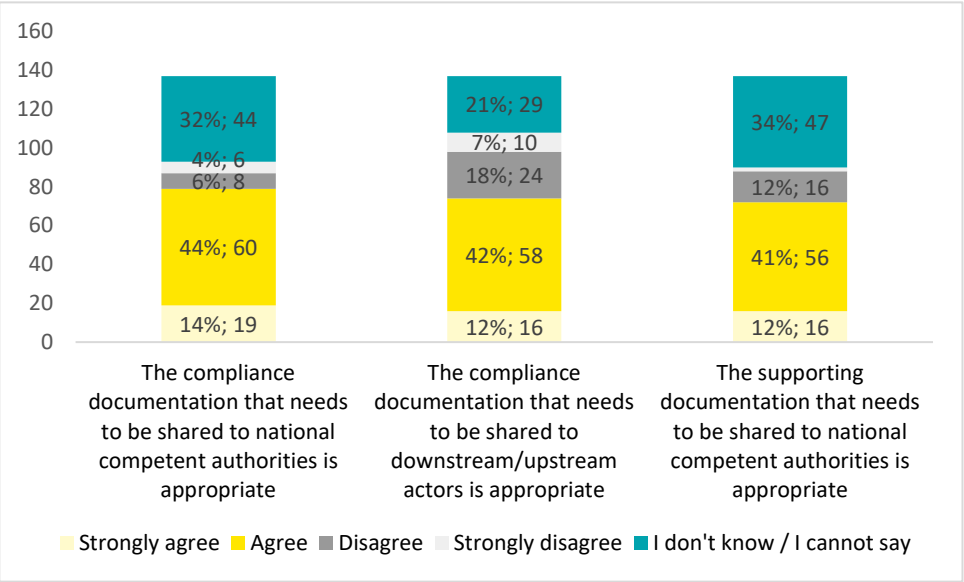


Figure 11 Question 10. In relation to the information currently exchanged for harmonized substances, how would you rate the quality of information provided by upstream/downstream actors? (137 respondents)

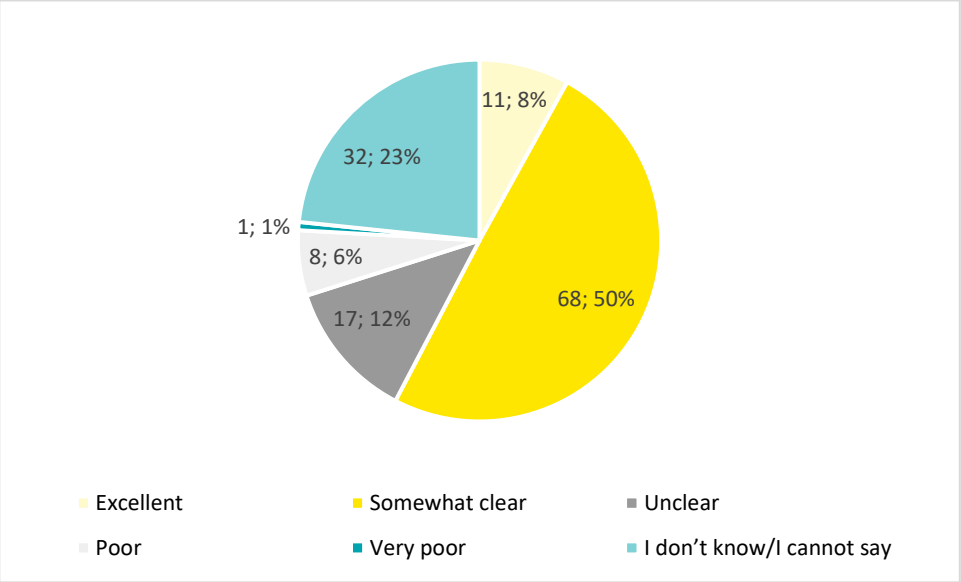
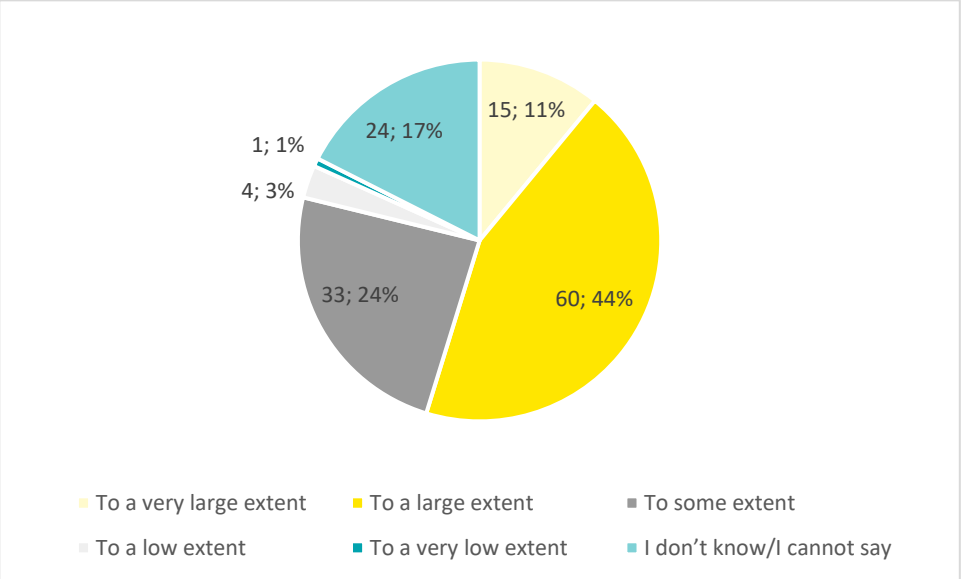


Figure 12 Question 11. For harmonized substances, to what extent are the current rules in place to ensure compliance clear and easily understandable? (137 respondents)



5.1.3 Resources

Figure 13 Question 12. In relation to the resources available in your organization for information exchange between actors in the supply chain, can you estimate the time spent on compliance activities per week (83 respondents)

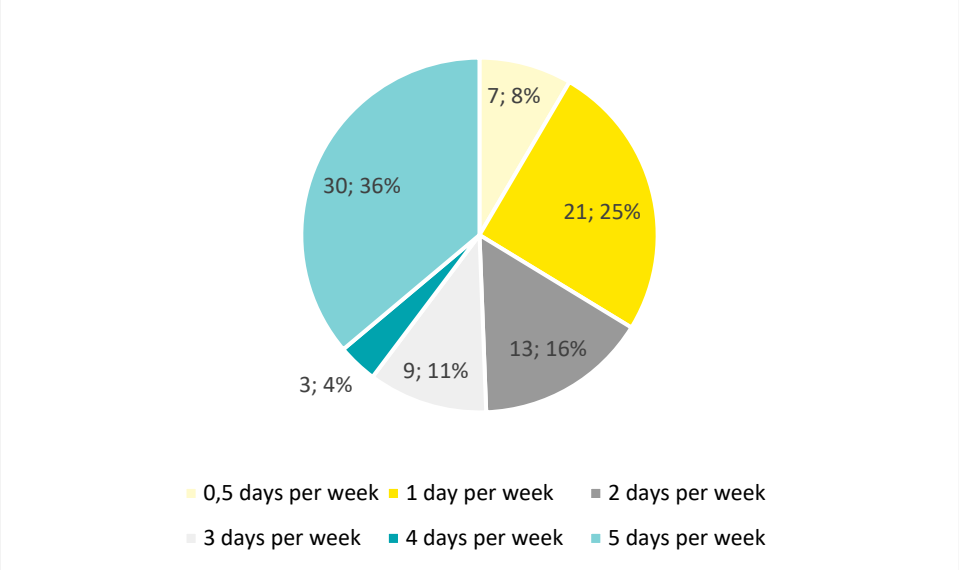


Figure 14 Question 13. To what extent would the use of digital formats for the exchange of information between actors within the supply chain reduce the time spent by your organization/the organizations that you represent? (129 respondents)

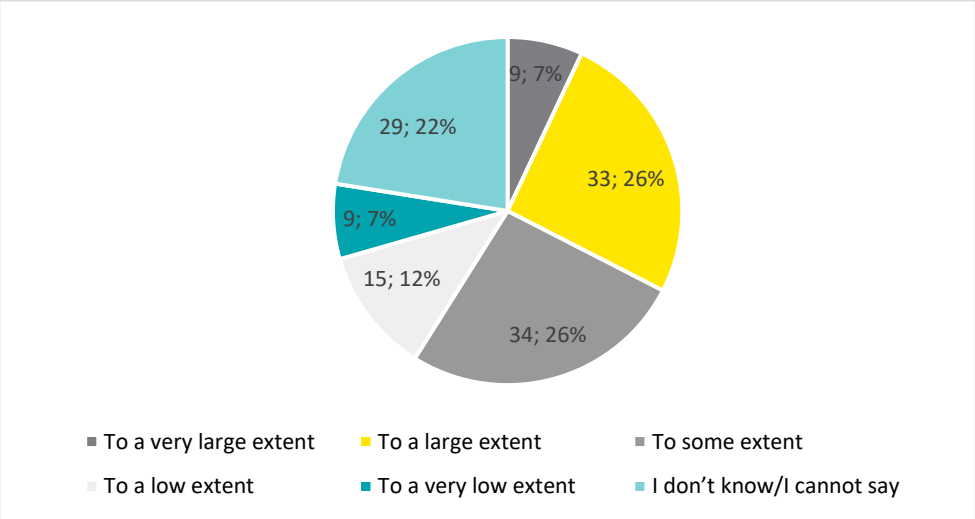


Figure 15 Question 14. How much time did it take your business to become fully functional in ensuring the compliance requirements associated with FCM? (83 respondents)

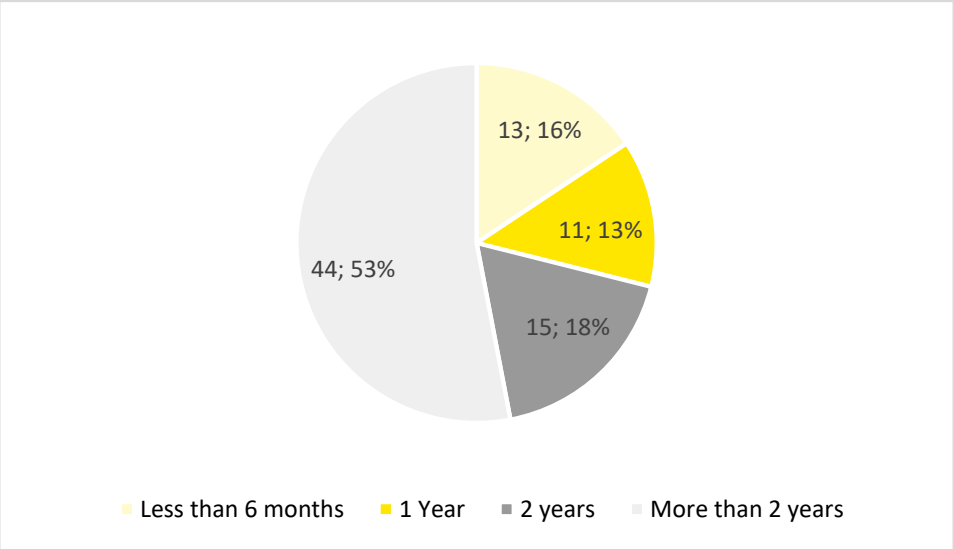


Figure 16 Question 15. Can you please detail how your organization currently stores safety and compliance information in-house? (83 respondents)

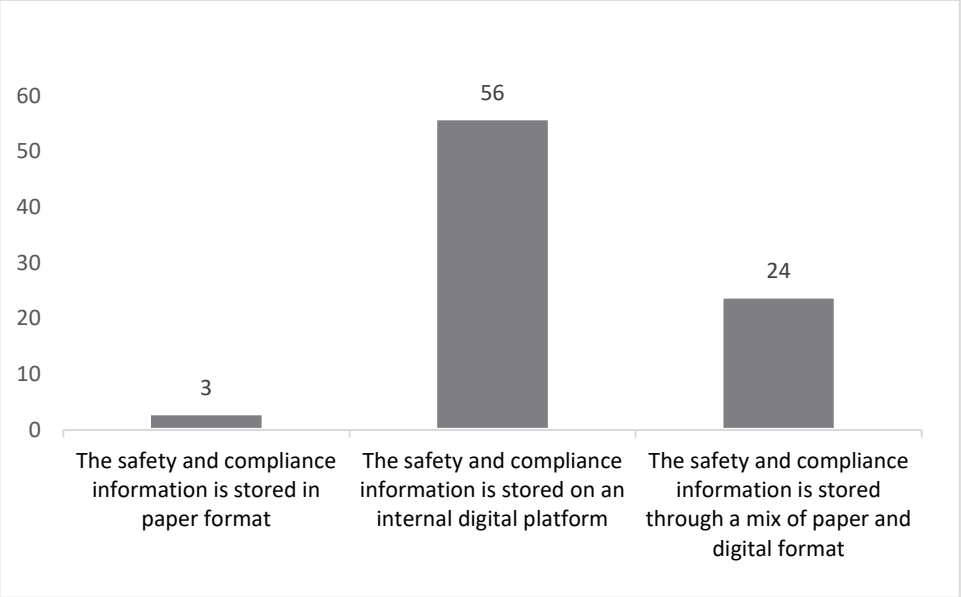
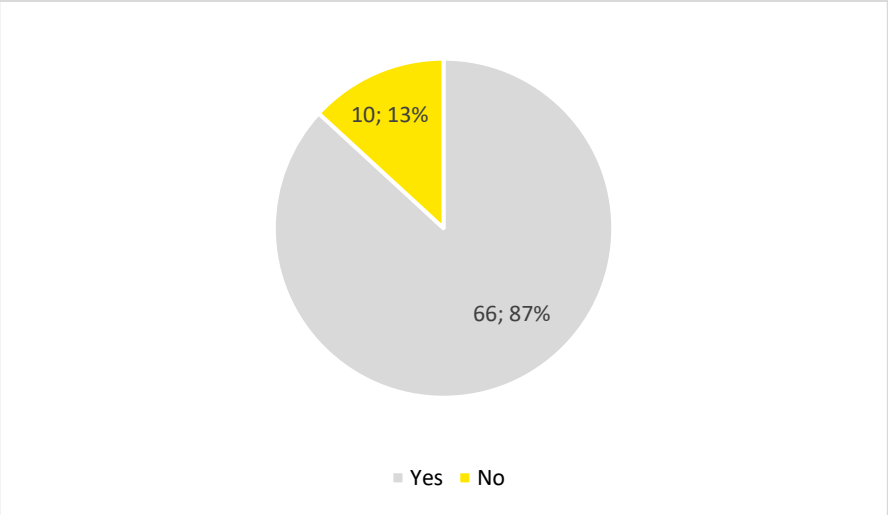
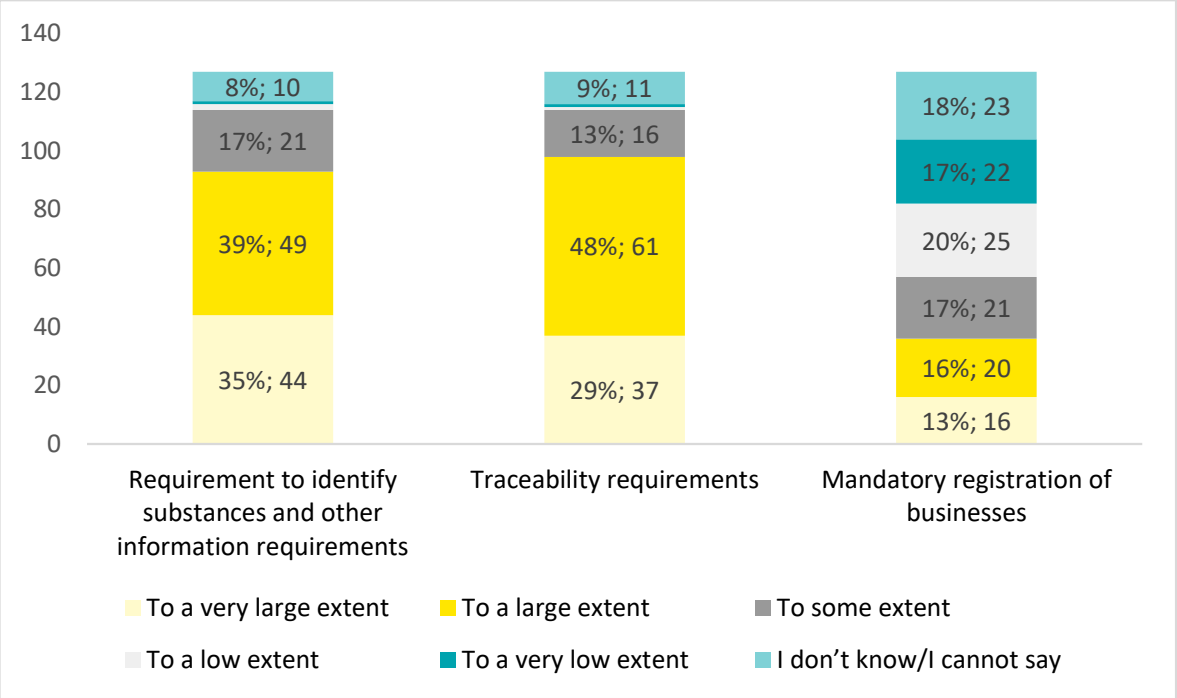


Figure 17 Question 17. Has your business needed to invest in new tools or resources to guarantee compliance requirements in relation to FCM? (76 respondents)



5.1.4 Risk management of FCM substances

Figure 18 Question 18. To what extent do you agree that the following tools are appropriate for the risk management of FCM substances? (127 respondents)



Information to be exchanged

Figure 19 Question 19. How do you currently exchange compliance documentation with actors in the FCM supply chain (e.g., manufacturers, other business operators)? Please select one or more of the following options: (75 respondents)

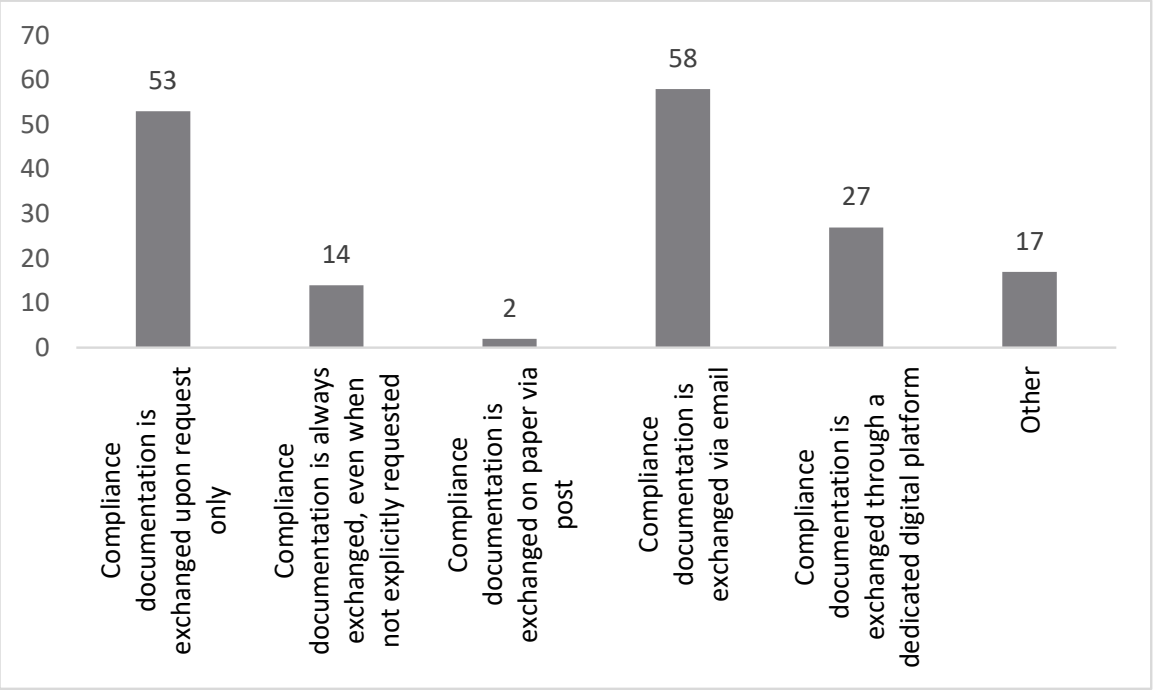


Figure 20 Question 20. What additional information do you exchange with actors in the FCM supply chain (e.g., manufacturers, other business operators)? (74 respondents)

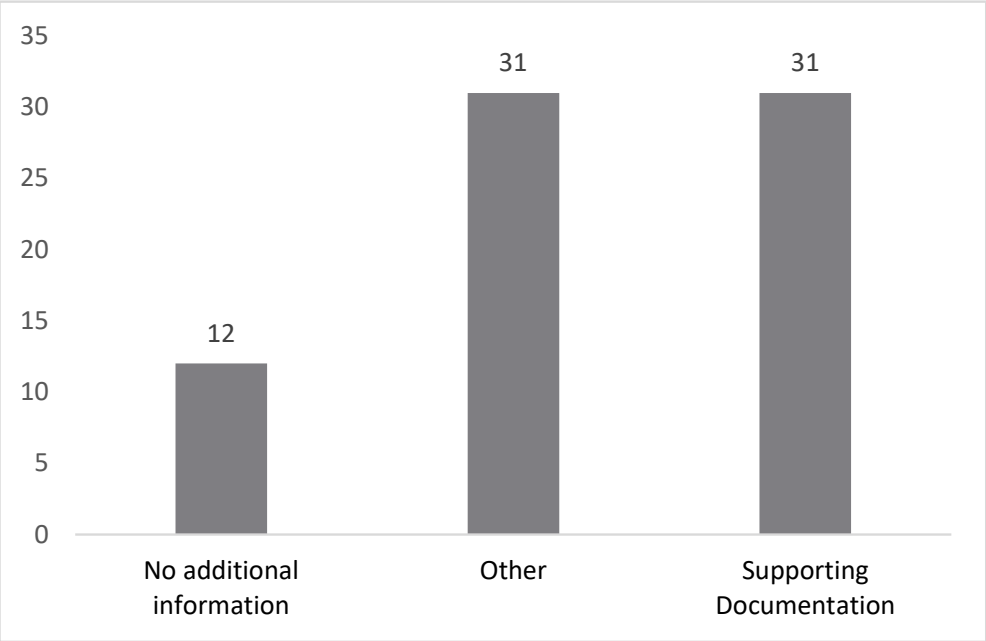


Figure 21 Question 21.How do you currently exchange additional information with actors in the FCM supply chain (e.g., manufacturers, other business operators)? Please select one or more of the following options (72 respondents)

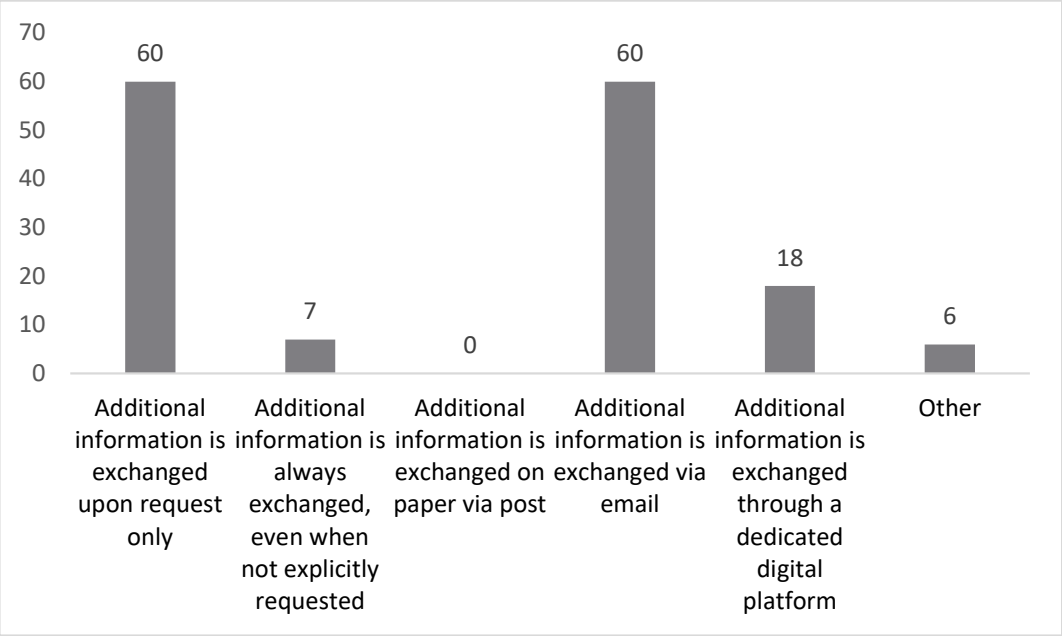


Figure 22 Question 22. How often (on average) do you need to reiterate the request for compliance documentation, Supporting Documentation and/or other documentation to actors in the supply chain to be able to complete your compliance activities? (75 respondents)

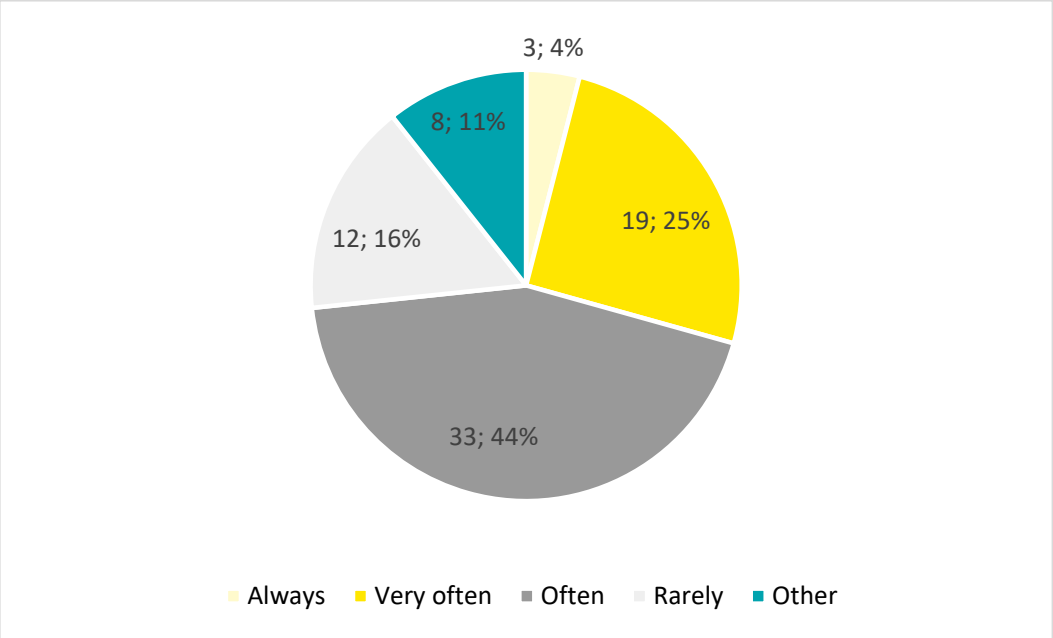


Figure 23 Question 23. How do you currently exchange compliance documentation and Supporting Documentation with National Authorities (NCA and NRL) in your Member State for the verification of compliance of FCM activities? Please select one or more of the following options

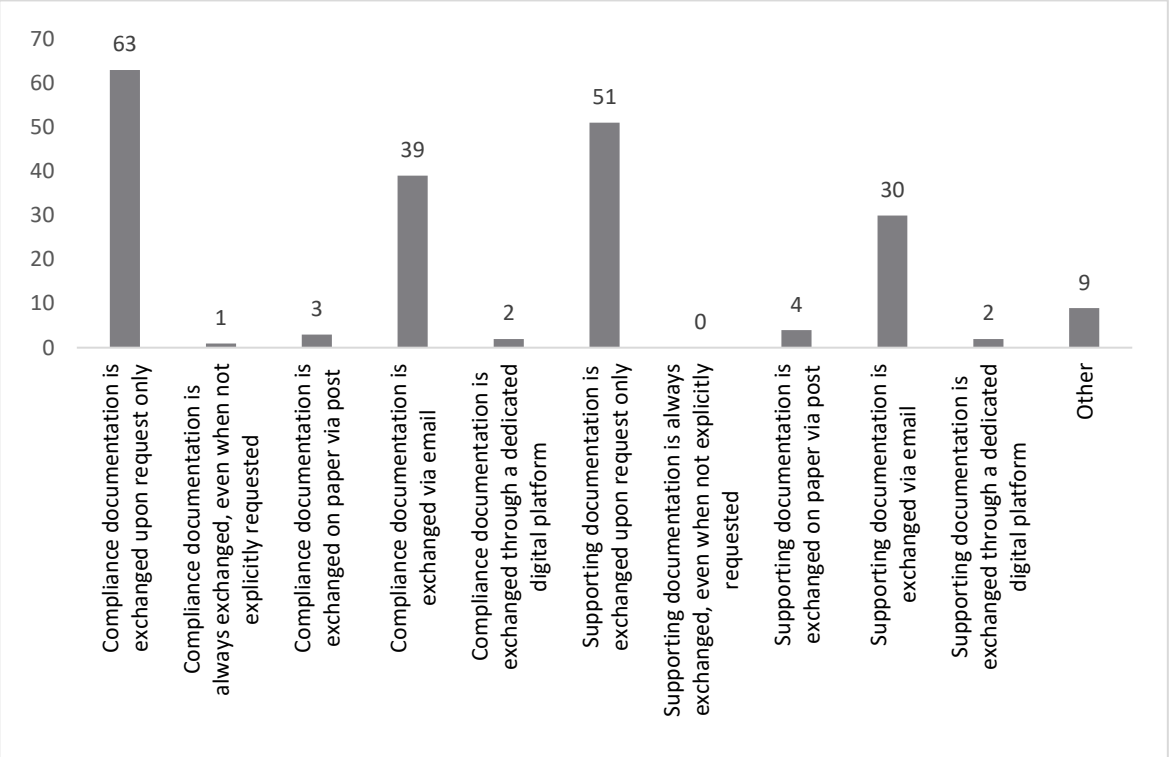


Figure 24 Question 24. What additional information do you exchange with National Authorities (NCA and NRL) in your Member State for the verification of compliance of FCM activities? (74 respondents)

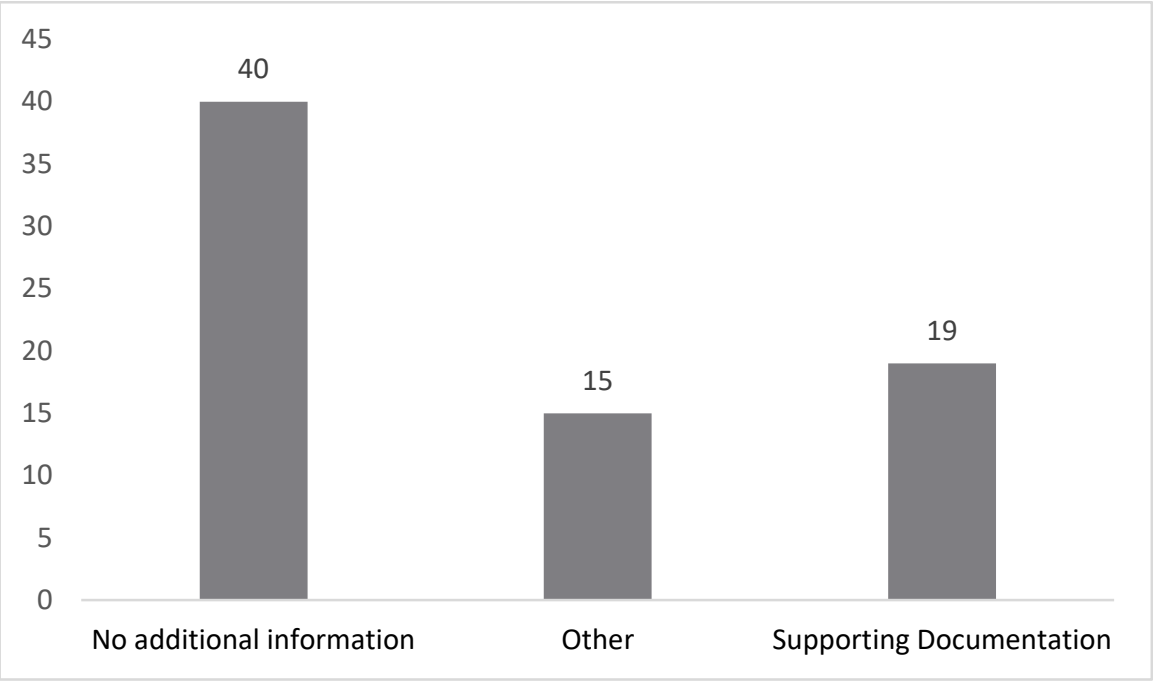


Figure 25 Question 25. How do you currently exchange additional information with National Authorities (NCA, NA, NRL) in your Member State for the verification of compliance of FCM activities? Please select one or more of the following options (66 respondents)

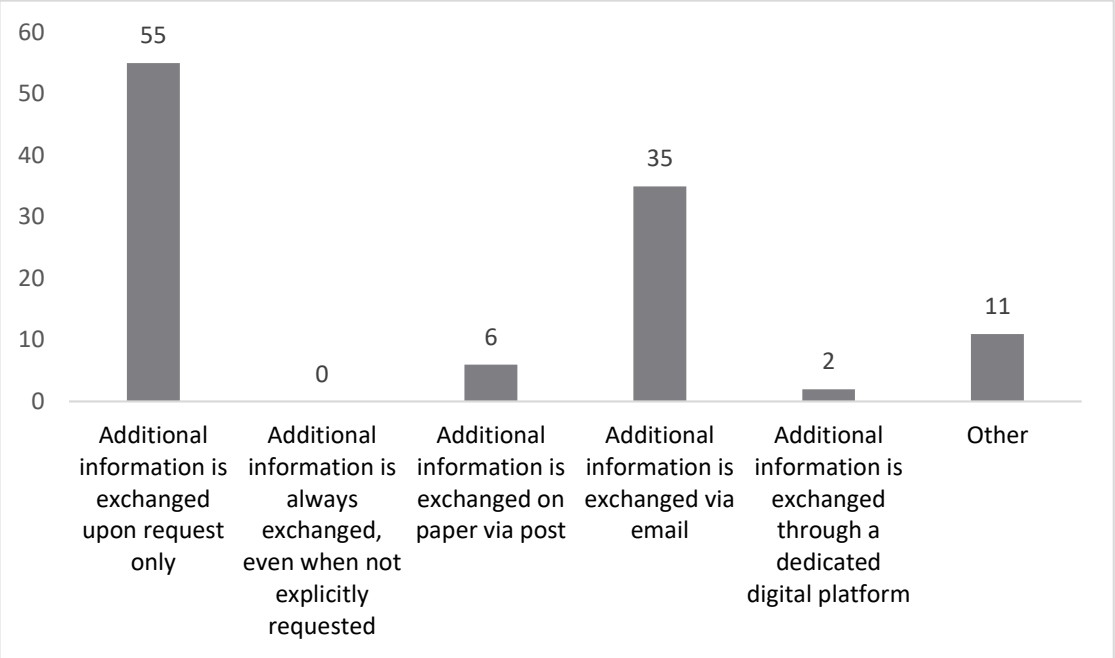


Figure 26 Question 26. Concerning the demonstration of compliance in the FCM production chain, to what extent do you agree with the following? (118 respondents)

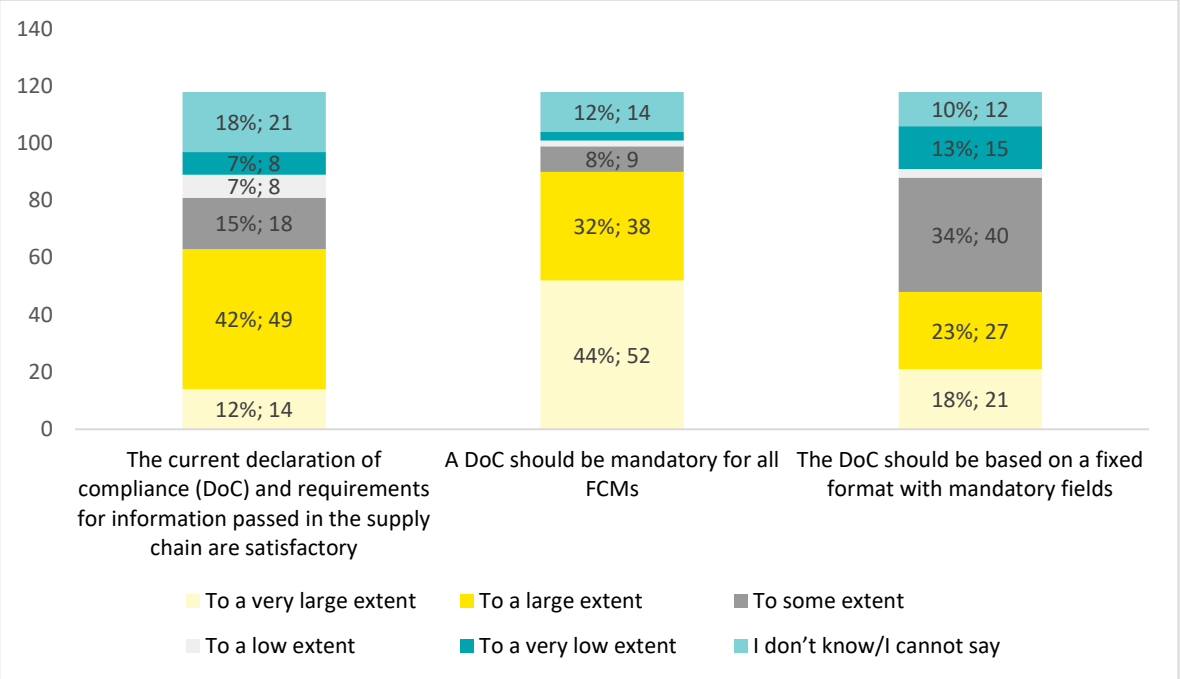


Figure 27 Question 27. Concerning the Declaration of Compliance for harmonized substances, to what extent do you consider the templates provided to be user-friendly and complete? (118 respondents)

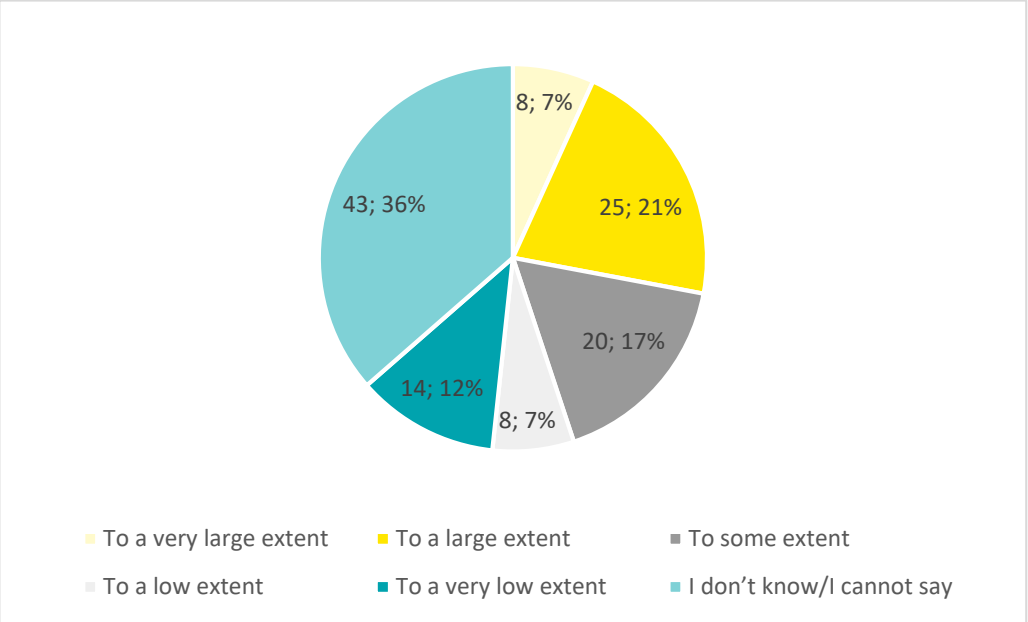


Figure 28 Question 28. In relation to exchange of compliance information with importers from third countries, how would you rate the quality of information received? (118 respondents)

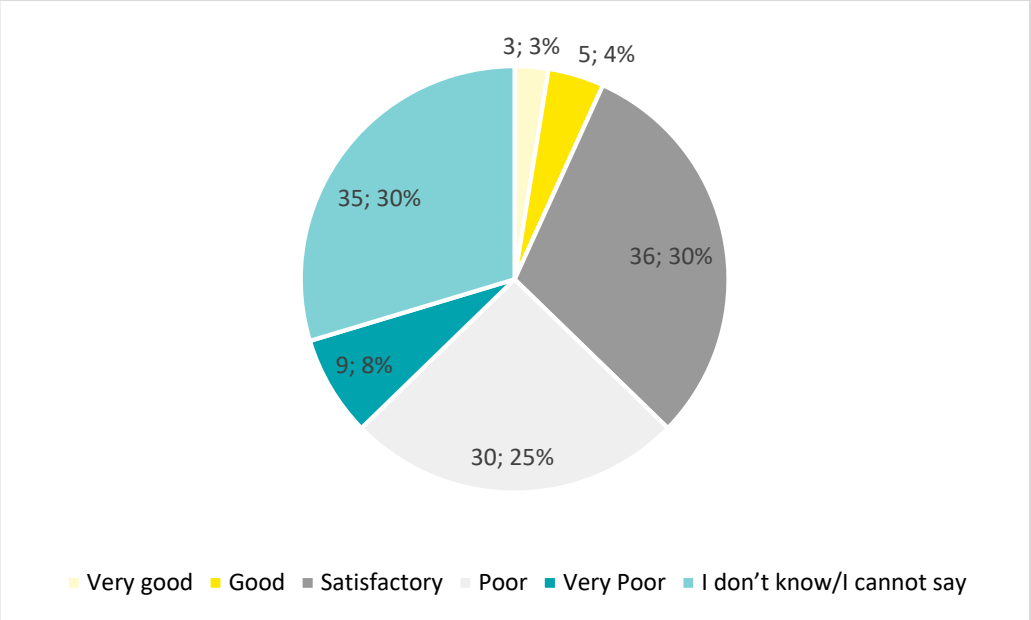


Figure 29 Question 29. With regard to the availability of information, to what extent do you agree with the following statements:

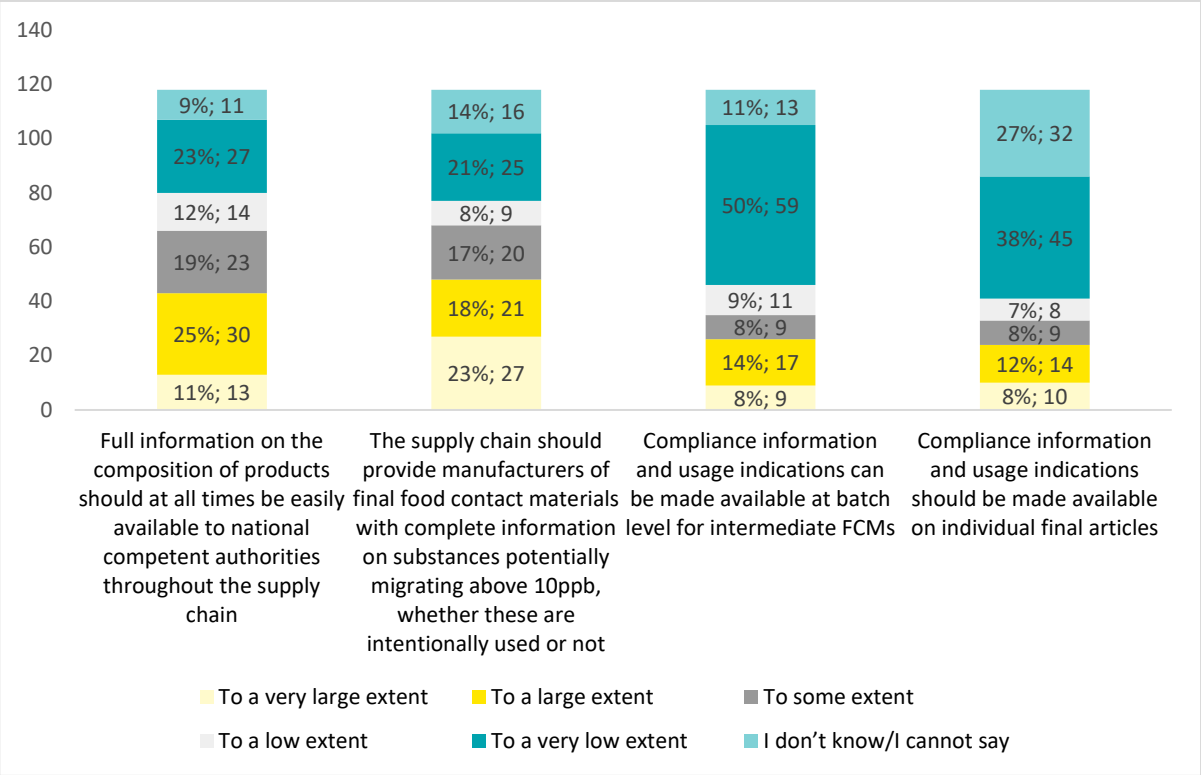


Figure 30 Question 30. To what extent do you agree that the following information should be required to pass from one business to the next in the production chain, to determine the eventual compliance of the FCM article (118 respondents)

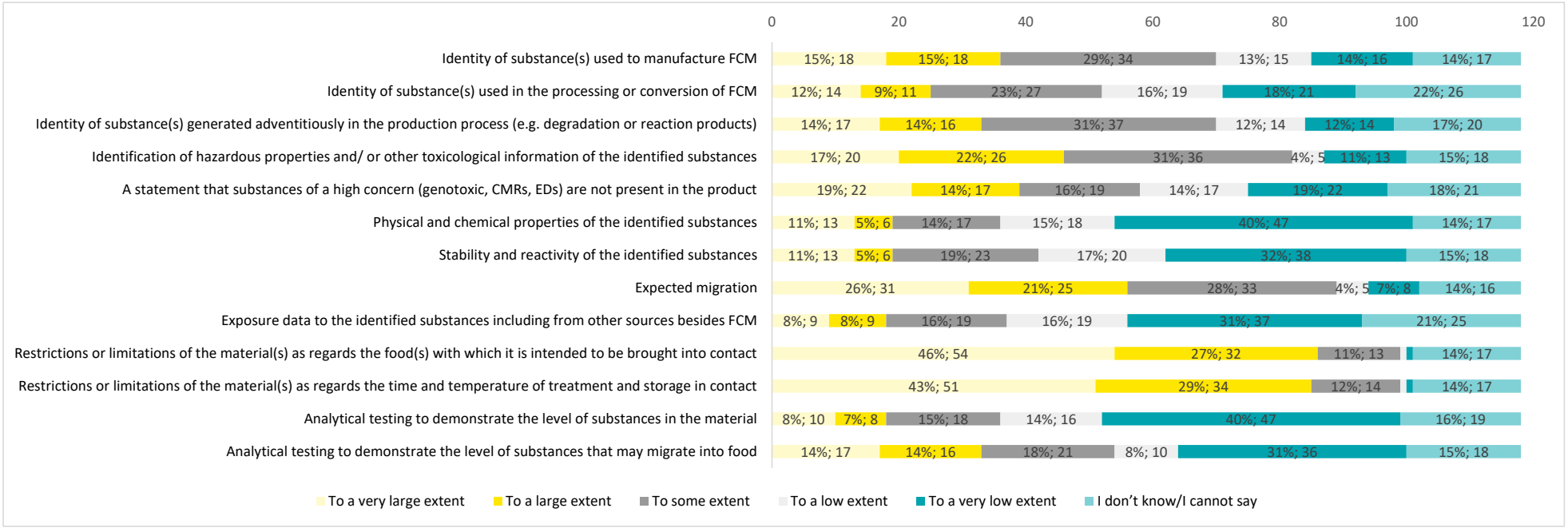


Figure 31 Question 33. Concerning a system for transfer of information in the supply chain, to what extent do you agree with the following statements: (110 respondents)

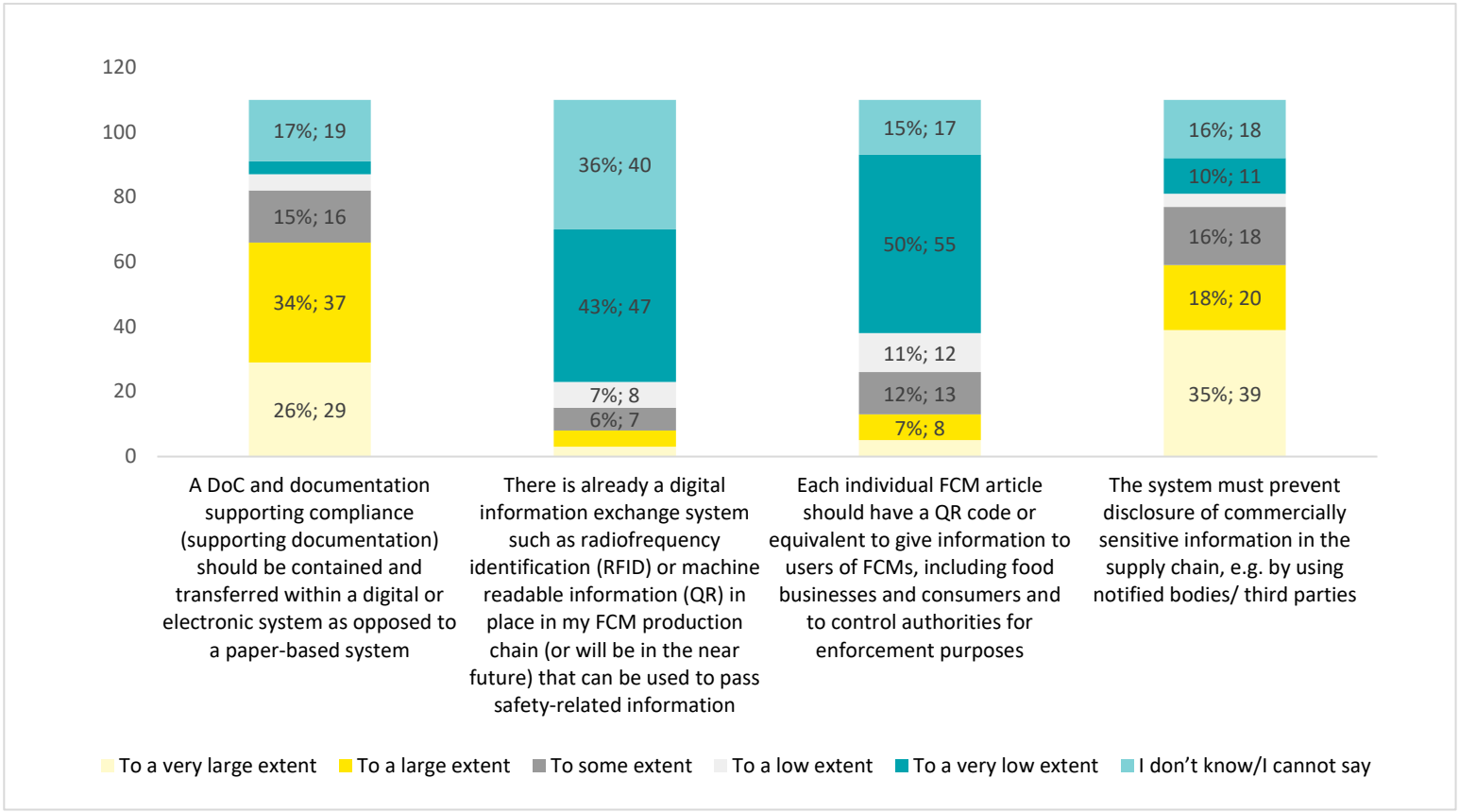


Figure 32 Question 34. Concerning the roles and responsibilities of the different actors, to what extent do you agree with the following statements: (110 respondents)

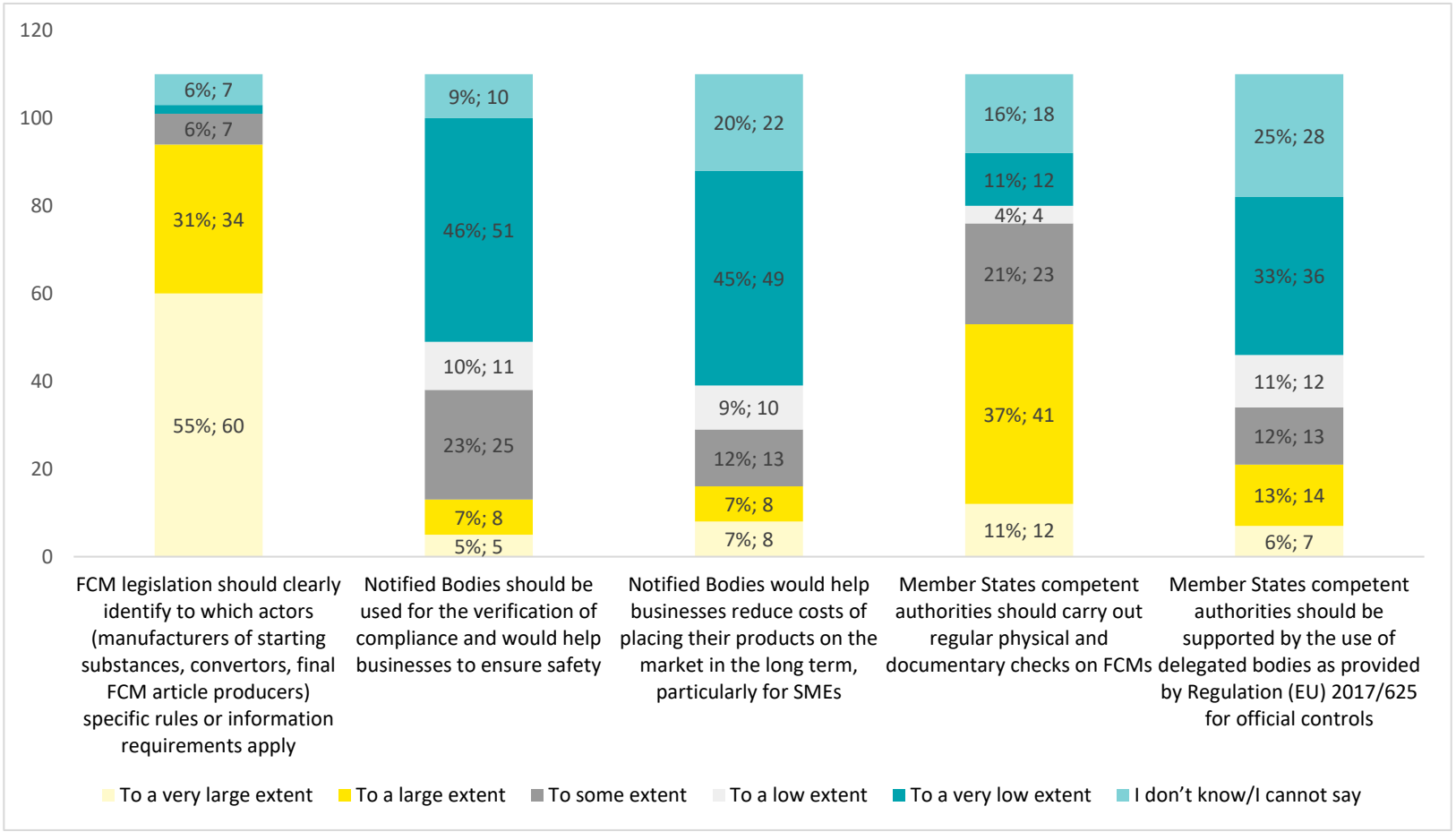


Figure 33 Question 35. Please rank from one (most relevant) to three (least relevant) the potential solutions for improving information exchange (109 respondents)

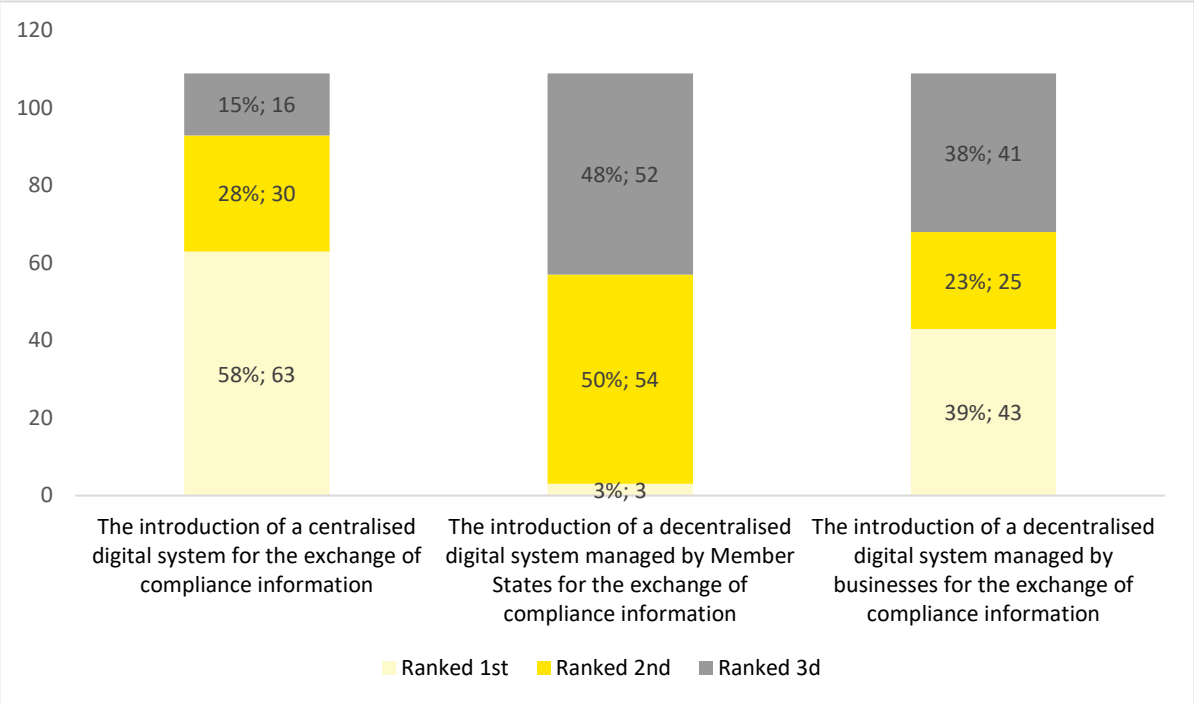


Figure 34 Question 38. To what extent would you agree with the following statements:

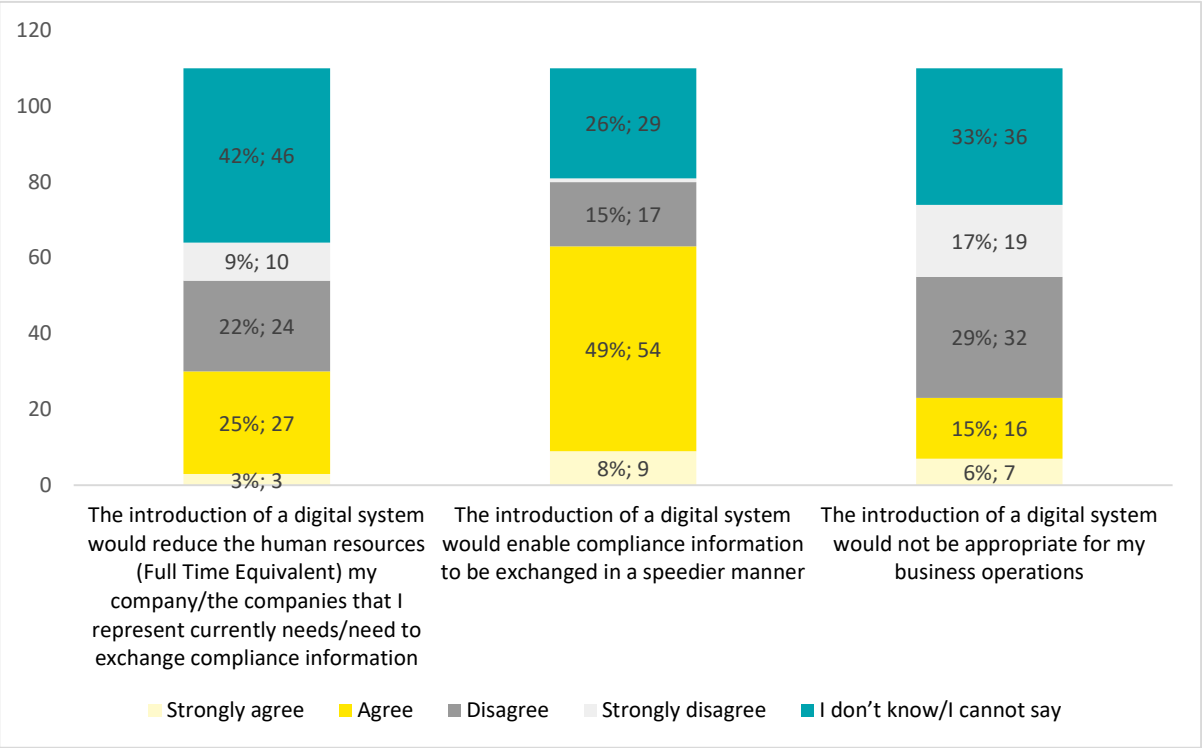


Figure 35 Question 39a. To what extent do you agree with the following advantages of introducing an IT infrastructure on a centralized system? (104-105 respondents according to the item)

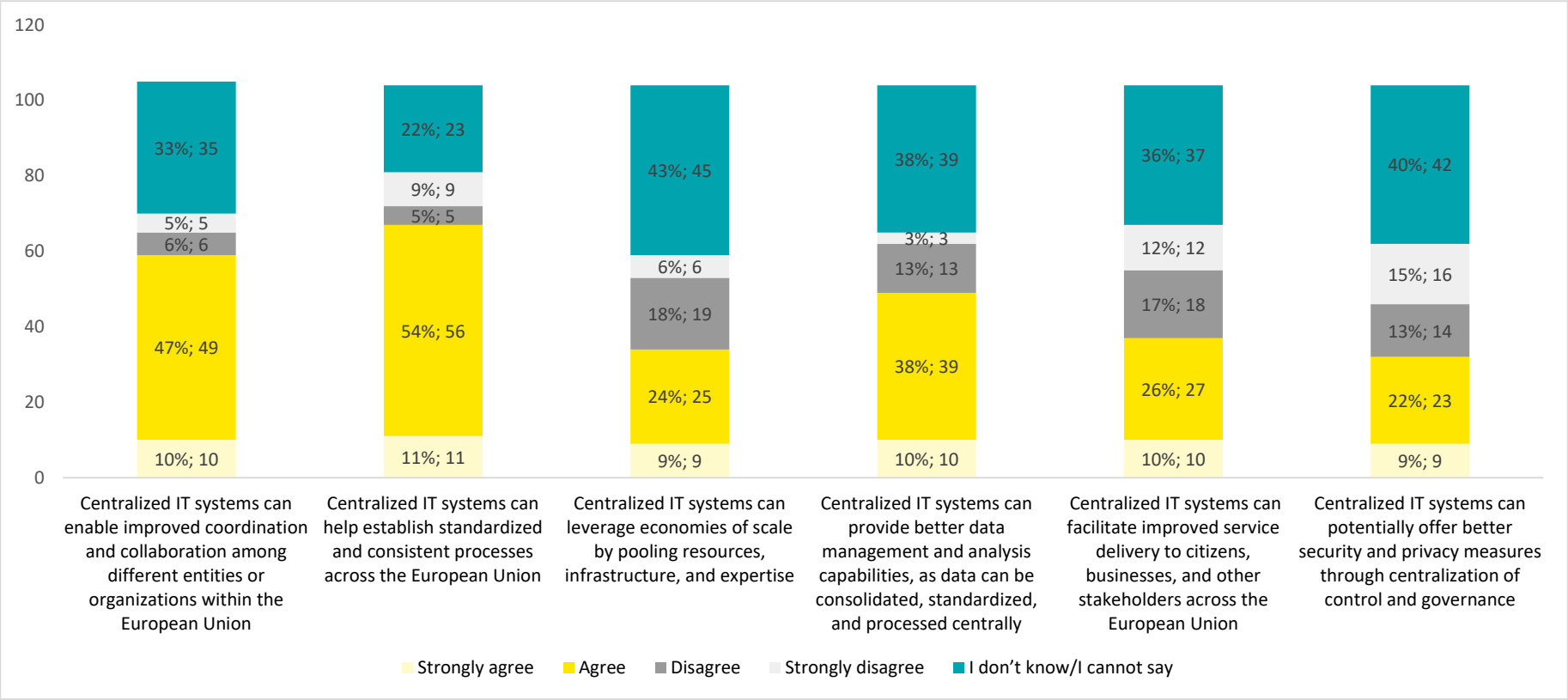


Figure 36 Question 39b. To what extent do you agree with the following disadvantages of introducing an IT infrastructure on a centralized system? (103-104 respondents according to the item)

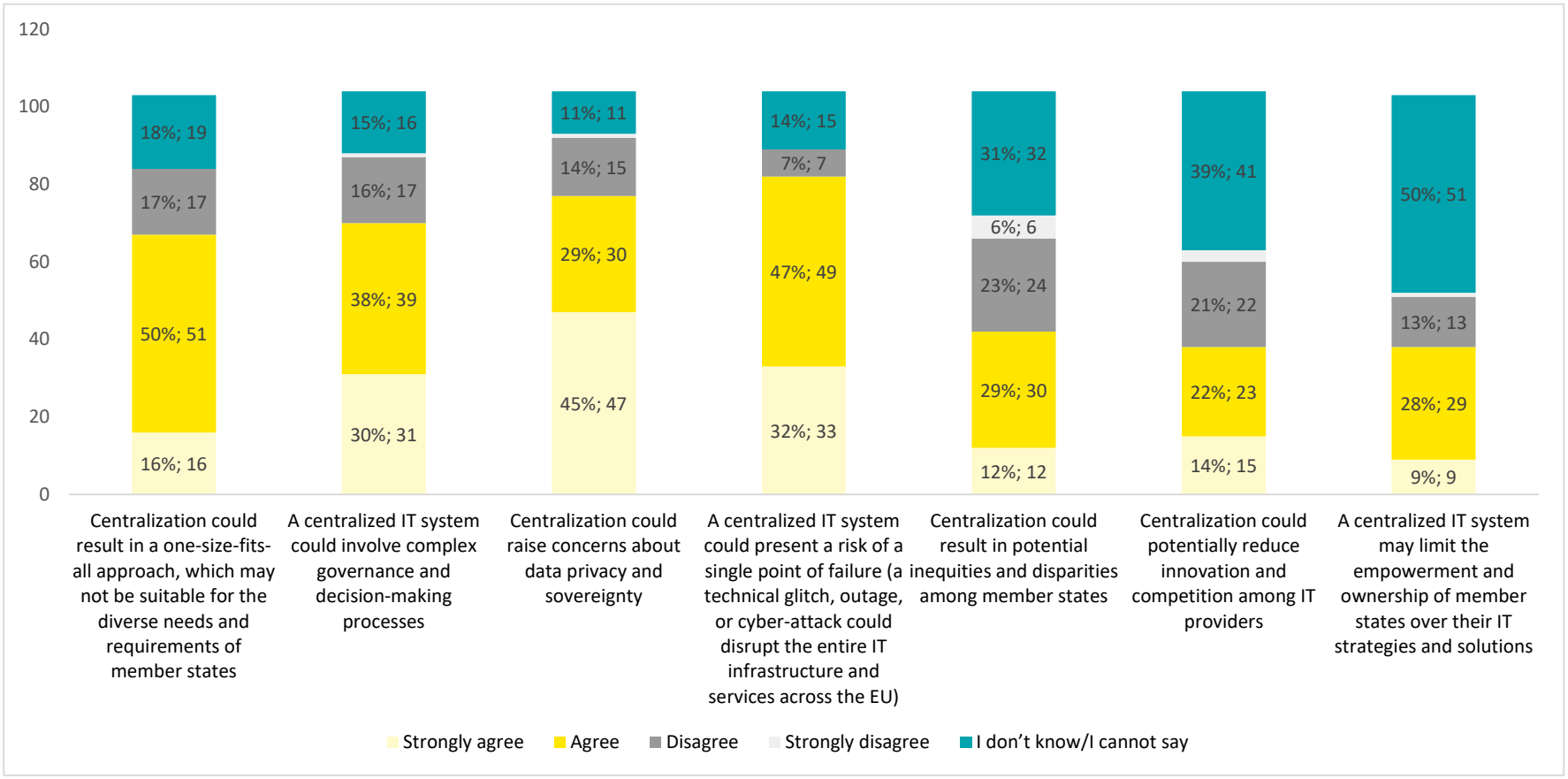


Figure 37 Question 40a. To what extent do you agree with the following advantages of introducing an IT infrastructure on a decentralized system? (101 respondents)

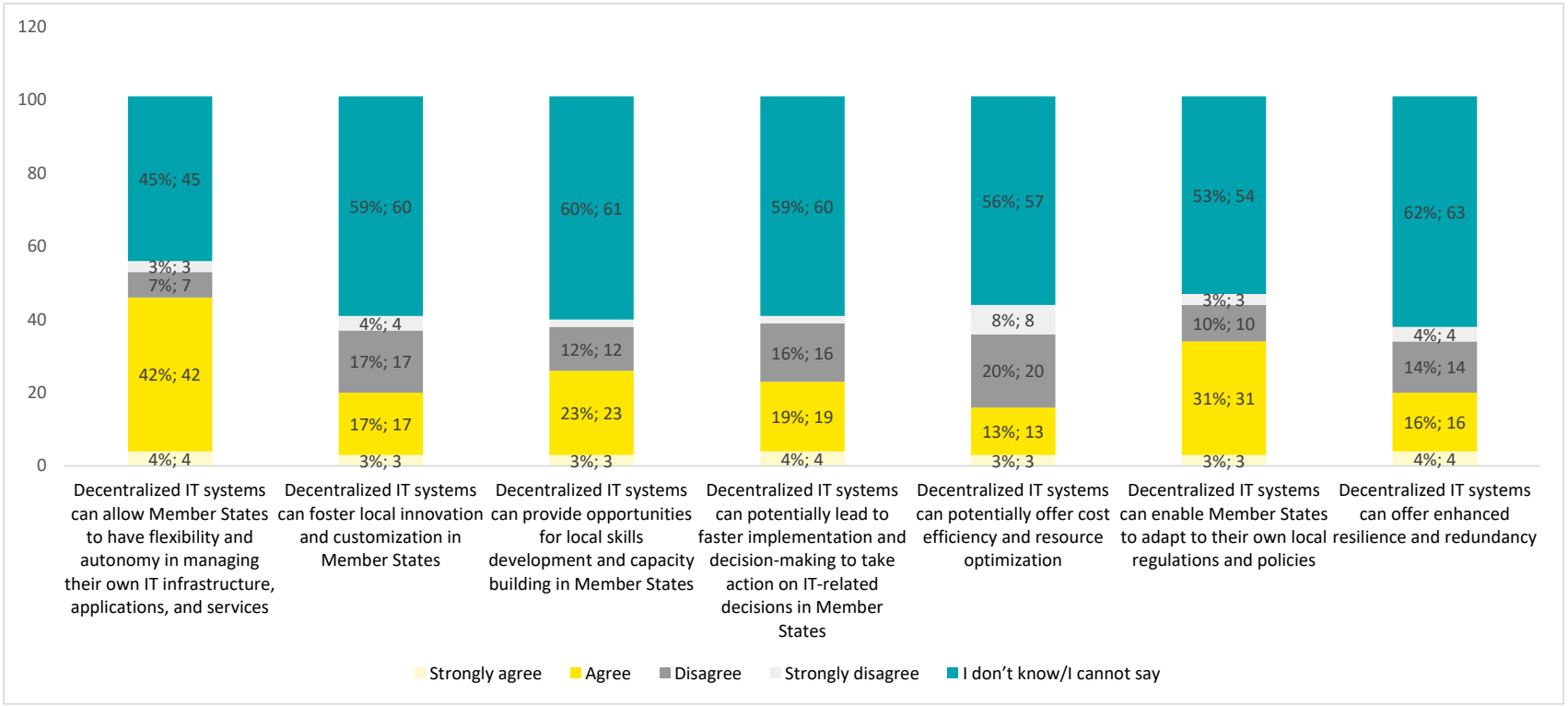
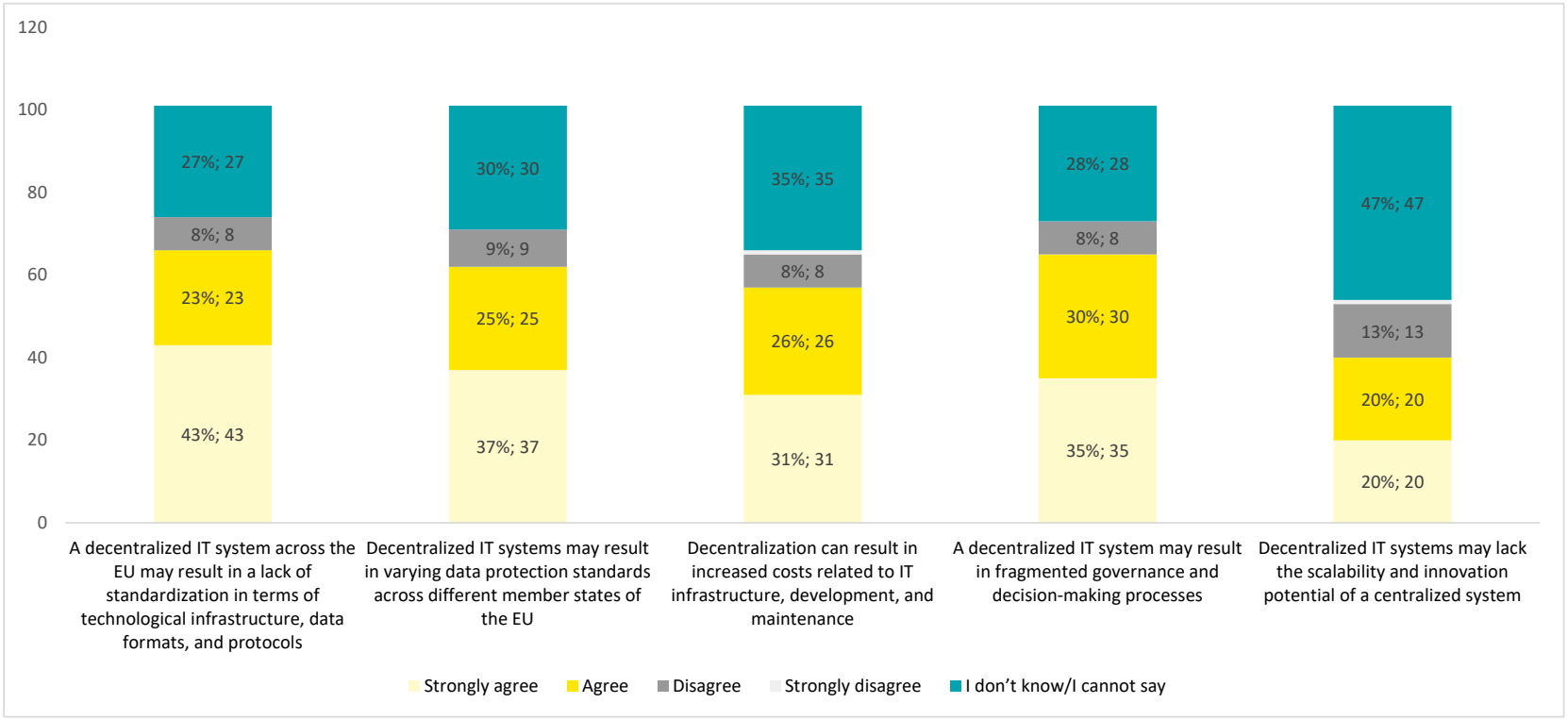


Figure 38 Question 40b. To what extent do you agree with the following disadvantages of introducing an IT infrastructure on a decentralized system? (101 respondents)



5.2. List of stakeholders consulted for online questionnaire

The below Table presents the list of EU-level professional and business associations concerning food contact materials identified by the European Commission to be consulted with and disseminate an online survey to their respective industries.

Table 1 EU-Level business associations to disseminate online surveys

EU Level Business Associations	
Industry	**Name of association**
Active and intelligent materials	Active and Intelligent Packaging Industry Association (AIPIA)
Adhesives	Association of the European Adhesive and Sealant Industry (FEICA)
Ceramics	The European Ceramic Industry Association (Ceramie Unie)
	European Enamel Association (EEA)
Glass	Glass Alliance Europe (alliance of glass industries composed of 13 national glass associations)
	European Container Glass Federation (FEVE)
	European Domestic Glass (EDG)
	European Special Glass Association (ESGA)
	Glass Fibre Europe (GFE)
	Glass for Europe (GFE)
Metals	Metal Packaging Europe
	Association of European Producers of Steel for Packaging (APEAL)
	European Aluminum (EA)
	Nickel Institute (NI)
	The European Steel Association (EUROFER)
Paper & board	Confederation of European Paper Industries (Cepi)
	European Carton Makers Association
	ACE (Alliance for Beverage Cartons and the Environment)
	The International Confederation of Paper and Board Converters in Europe (CITPA)
Plastics	The Committee of PET Manufacturers in Europe (CPME)

	European Bioplastics
	PlasticsEurope
	European Plastics Converters (EUPC)
	European Chemical Industry Council (CEFIC) – FCA (Food Contact Additives) Sector Group and SOIA
	Petcore Europe
	Flexible Packaging Europe
	Plastic Recyclers Europe
Food contact chemicals	European Chemical Industry Council (CEFIC) – FCA (Food Contact Additives) Sector Group
Other packaging	EUROPEN - The European Organization for Packaging & the Environment
	European Corrugated packaging Association (FEFCO)
Printing Inks	European Printing Ink Association
	I&P Europe - Imaging and Printing Association
	European Federation for Print and Digital Communication (INTERGRAF)
Wax	European Wax Federation
Regenerated Cellulose	Comité International de la Pellicule Cellulosique (CIPCEL)
Rubber	European Tyre & Rubber Manufacturers Association (ETRMA)
Silicone	Silicones Europe (CES)
Textiles	European Disposables and Nonwovens Association (EDANA)
Varnishes and Coatings	European Council of the Paint, Printing Ink and Artists' Colours Industry (CEPE)
Wood	European Confederation of Woodworking Industries (CEI-BOIS)
Other	APPLiA Home Appliance Europe (APPLiA)
	European Liaison Committee for Agriculture and agri-food trade (CELCAA)
	Chemical Recycling Europe (ChemRecEurope)
	Eurocolour
	Extended Producer Responsibility Alliance (EXPRA)
	FoodDrinkEurope
	Independent Retail Europe
	European Industrial Minerals Association (IMAEurope)
	European Association of Craft, Small and Medium-sized Enterprises (SMEunited)
	European Soft Drinks Association (UNESDA)
	World Association of Manufacturers of Bottles and Teats (WBT)

5.3. List of stakeholders consulted for written questionnaire

5.3.1. National Authorities and National Competent Authorities consulted for Written Questionnaires

The Table below presents a list of the National Competent Authorities as defined by DG SANTE of the Commission as of December 2022[23]. It includes Government ministries for health and/or agriculture, government agencies for health and food safety and other institutions under the purview of government such as national centers for public health and other laboratories. The delegation of responsibilities with regard to the creation of national FCM legislation, FCM application and controls for compliance within each MS can vary, as can the level of decentralization with respect to these responsibilities[24]. The following list of NA/NCA have been requested to fill in a written questionnaire. The following table also indicates which Member States have provided a response (n=23), as well as the ones for which we are still awaiting a response (n=6).

Table 2 NAs and NCAs consulted for written questionnaire

NAs and NCAs		
Member State	**Authority**	**Status of response**
Austria	Federal Ministry for Social Affairs, Health, Care and Consumer Protection (BMSGPK)	Received
Belgium	Federal Public Service Health, Food chain safety and Environment	Received
	Federal Agency for the Safety of the Food Chain	
Bulgaria	Ministry of Health	Received
	National Center of Public Health and Analyzes	
	Bulgarian Food Safety Agency	
Croatia	Ministry of Health	Not received
Cyprus	Ministry of Health, Medical and Public Health Services	Received
	State General Laboratory (Ministry of Health)	
Czech Republic	Ministry of Health	Not received
	National Institute of Public Health	
Denmark	Danish Veterinary & Food Administration	Received
Estonia	Ministry of Rural Affairs	Received
	Agriculture and Food Board	
Finland	Ministry of Agriculture and Forestry	Received
	Finnish Food Authority Ruokavirasto	

[23] European Commission (2022) – *Contact points for the competent authorities of the Member States and other countries for Food Contact Materials.* cs_fcm_auth_ref_en.pdf (europa.eu)

[24] For example, in the preliminary interviews, we found that the Danish Vetenary and Food Administration is responsible for the creation of FCM regulation as well as enforcement. For Germany on the other hand,

NAs and NCAs		
France	Ministry of Economy and Finance – Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF)	Received
Germany	Federal Ministry for Food and Agriculture (BMEL)	Received
	The Federal Office of Consumer Protection and Food Safety (BVL)	
Greece	Independent Authority for Public Revenue – General Directorate of General Chemical State Laboratory	Received
	Hellenic Food Authority (EFET)	
Hungary	Ministry of Agriculture	Received
	National Food Chain Safety Office	
Ireland	Food Safety Authority of Ireland	Not received
	Department of Agriculture, Food and the Marine	
Italy	Ministry of Health	Received
Latvia	Ministry of Agriculture	Received
	Food and Veterinary Service	
Lithuania	Ministry of Health	Received
	State Food and Veterinary Service	
Luxembourg	Ministère de l'agriculture, de la viticulture et du développement rural	Received
Malta	Malta Competition and Consumer Affairs Authority	Received
	Food safety Commission	
Poland	Chief Sanitary Inspectorate	Received
Poland	National Institute of Public Health NIH - National Research Institute	
Portugal	Ministério da Agricultura e Alimentação	Received
Romania	National Institute of Public Health	Not received
Slovak Republic	Public Health Authority of SR	Received
	Regional Public Health Authority in Poprad	
Slovenia	Ministrstvo za zdravje/ Ministry of Health	Received
Spain	Ministry of Consumer affairs – Spanish Agency for Food Safety and Nutrition	Received
Sweden	Livsmedelsverket/ Swedish National Food Agency	Received
The Netherlands	Ministry of Health, Welfare and Sport	Not received
The Netherlands	Dutch National Institute for Public Health and the Environment (RIVM)	
Iceland	Icelandic Food and Veterinary Authority	Not received

NAs and NCAs		
Iceland	Ministry of Industries and Innovation	
Norway	Mattilsynet/ Norwegian Food Safety Authority	Received

5.3.2. National Reference Laboratories consulted for Written Questionnaires

The table below presents the list of National Reference Laboratories identified in cooperation with the European Commission and with which we have shared a written questionnaire. The table also indicates which NRLs have provided a response to the date of this report.

Table 3 National Reference Laboratories consulted for written questionnaire

Network of National Reference Laboratories		
Member State	**Name**	**Status of response**
Austria	Austrian Agency for Health and Food Safety	Received
Belgium	Institute of Public Health	Not received
Bulgaria	National Center of Public Health and Analysis	Not received
Croatia	Croatian National Institute of Public Health	Not received
Cyprus	Laboratory for Control of Food Contact Materials and Control of Toys, Ministry of Health	Not received
Czech Republic	National Institute of Public Health	Not received
Denmark	Research group for analytical food chemistry, National Food Institute, Technical University of Denmark	Received
	Danish Veterinary and Food Administration Laboratory Århus	
Estonia	Health Board, Health and Safety Laboratory - Laboratory of Tallinn	Not received
Finland	Finnish Customs Laboratory	Not received
France	Testing Department - Laboratoire National d'Essais	Not received
	SCL Laboratoire de Bordeaux-Pessac	
Germany	National Reference Laboratory for Materials in contact with food, Federal Institute for Risk Assessment	Received
Greece	General Chemical State Laboratory	Received
Hungary	National Food Chain Safety Office, Food and Feed Safety Directorate	Received
Ireland	Public Analyst's Laboratory	Not received
Italy	Instituto Superiore di Sanità	Not received

Network of National Reference Laboratories		
Latvia	Institute of Food Safety, Animal Health and Environment "BIOR"	Not received
Lithuania	National Public Health Surveillance Laboratory, Laboratory of Chemistry	Not received
Luxembourg	Laboratoire National de Santé	Not received
Malta	Ministry for Social Policy Public Health Laboratories	Not received
Poland	Laboratory of Department of Food Safety, National Institute of Public Health	Not received
Portugal	ESB (Portuguese Catholic University - Biotechnology College – Packaging Department	Not received
Romania	National Reference Laboratory for Food Contact Materials - National Institute of Public Health	Not received
Slovak Republic	National Reference Center and Laboratory for material and articles intended to come into contact with food, Regional Public Health Authority in Poprad (RUVZ)	Not received
Slovenia	National Laboratory of Health, Environment and Foodstuffs, Center for Environment and Health	Not received
Spain	National Food Center, Spanish Agency for Food Safety and Nutrition	Received
Sweden	National Food Administration, Chemistry Division	Not received
The Netherlands	The Netherlands Food and Consumer Product Safety Authority, Ministry of Economic Affairs, Agriculture, and Innovation	Not received
Observers		
Switzerland	Official Food Control Authority of the Canton of Zurich	Not received

5.4. List of stakeholders consulted for Targeted Interviews

5.4.1. Member States consulted for Targeted interviews

Table 4 Selection of countries interviewed

Country	Phase of interviews
Austria	First phase
Denmark	First phase
France	First phase
Germany	First phase
Greece	First phase

Hungary	First phase
Poland	First phase
Portugal	Second phase
Estonia	Second phase
Belgium	Second phase
Netherlands	Second phase
Norway	Second phase
Slovenia	Second phase
Slovakia	Second phase
Finland	Second phase

5.4.2. Industry associations consulted for Targeted interviews

Table 5 Overview of industries interviewed

Industry	EU Association	Phase of interviews
Ceramics	The European Ceramic Industry Association (Ceramie Unie)	First phase
Metals	Metal Packaging Europe	First and second phase
Plastics	Plastics Europe	First and second phase
Packaging	EUROPEN - The European Organization for Packaging & the Environment	First phase
Wax	European Wax Federation	First phase
Rubber	European Tyre & Rubber Manufacturers Association (ETRMA)	First phase
Adhesives	Association of the European Adhesive and Sealant Industry (FEICA)	First phase
Glass	Glass Alliance Europe	First phase

Industry	EU Association	Phase of interviews
Wood	European Confederation of Woodworking Industries (CEI-BOIS)	First and second phase
Printing Ink	European Printing Ink Association - CEPE	First phase
Printing Ink - Can Coating	Can coating - CEPE	First phase
Paper and board	Confederation of European Paper Industries (Cepi)	First phase
Food and drink	FoodDrinkEurope	First phase
SMEs	European Association of Craft, Small and Medium-sized Enterprises (SMEunited)	First phase
Regenerated cellulose	Members of Comité International de la Pellicule Cellulosique (CIPCEL) Comité International de la Pellicule Cellulosique (CIPCEL)	First phase
Silicone	Silicones Europe	First phase
Consumers	BEUC	First phase
Food contact additives	Food Contact Additives Sector Group in CEFIC	First phase
Other	Flexible Packaging Europe Zero Waste Europe	First phase

5.4.3. EU-level organizations consulted for Targeted Interviews

Table 6 Overview of EU-level organizations interviewed

EU-level organizations
European Commission DG SANTE (Units A4, F1)
European Commission DG GROW (F1, F2)
European Chemicals Agency (ECHA) – Directorate of Risk Management (REACH)
European Committee for Food Contact Materials and Articles (CD-P-MCA)
European Food Safety Agency (EFSA)
EUDAMEN European Database on Medical Devices
TRACES

5.4.4. Interviews with representatives of IT systems

IT systems
IMDS
Digital Product Passport
EMVO

5.5. Results of Open Public Consultation (OPC)

On 20 May 2020, the European Commission published a Communication on a Farm to Fork Strategy, in which it commits to revise the EU legislation on food contact materials (FCMs), particularly including Regulation (EU) 1935/2004. In December 2020, an inception impact assessment was launched, identifying 5 objectives under two policy themes (Safety and Sustainability, Information exchange, Compliance and Enforcement): 1) Shifting the focus onto the final material, 2) Prioritisation of substances, 3) Supporting safer and more sustainable alternatives, 4) Improving quality and accessibility of supply chain information, 5) System for verifying compliance.

An open public consultation (OPC) aimed at collecting views of citizens and stakeholders, in order to support the impact assessment of the legislative revision of EU rules on FCMs, has taken place from 05 October 2022 to 11 January 2023. The current document aims at presenting the results about information exchange withing the FCM supply chain and enforcement of FCM rules on safety and compliance.

Profile of respondents

609 responses to the public consultation were received in total (n=609). When interpreting the results of the consultation, responses received cannot be understood as representing the views of any particular population or group of stakeholders. The questionnaire was publicly available on the Internet, and no one was precluded from providing a response. Information on the demographic profile of respondents is based on self-reported values and the survey design did not allow for any verification of received data.

The sample includes 282 responses (46%) submitted on behalf of citizens, among which 276 are EU citizens. Companies/Business organizations were the next largest group, accounting for 164 responses (27%), followed by business associations (n=83, 14%), public authorities (n=27, 4%), non-governmental organizations (n=22, 4%), academic/research institutions (n=16, 3%), consumer organizations (n=6, 1%), environmental organizations (n=6, 1%), and trade unions (n=2, <1%). The overview of contribution types is presented in Table 7.

Table 7: Overview of contribution types

I am giving my contribution as a/an	Count	Per cent
Academic/research institution	16	3%
Business association	83	14%
Company/business organization	164	27%
Consumer organization	6	1%
Environmental organization	6	1%
EU citizen	276	45%
Non-EU citizen	6	1%
Non-governmental organization (NGO)	22	4%
Other[25]	1	0%
Public authority	27	4%
Trade union	2	0%
Total	**609**	**100%**

A first analysis of the data brought out the need to recategorize 11 of the 12 respondents having answered "Other" to the question "I am giving my contribution as a/an", as presented in Table 2. The recategorization

[25] The data set provided included 12 responses filed under the "Other" field. Analysis of the answers "Name of organization" allowed 11 of them to be recategorized into a more specific category.

has been done on the basis of the organizations that the stakeholders have declared to be affiliated with. The only exception was a "Freelance project leader - Nutrition, Scientific & Regulatory Affairs", for which in effect no specific affiliation was identified. The recategorization further allows to provide a more precise analysis of responses to the OPC, given that responses are distributed across the correct stakeholder types. In addition, it allows to increase the number of answers considered in the analysis differentiated by stakeholder types.

Table 8: Recategorization of stakeholder type

Organization name	"I am giving my contribution as a/an" recategorization
Céramiste professionnelle, adhérente de l'association Terre et Terres	Company/business organization
Food Packaging Forum Foundation	NGO
Citeo	Company/business organization
Council of Europe/EDQM	Public authority
A.St.A. World-Wide	Company/business organization
Associazione italiana Città della Ceramica AiCc	Business association
Asociación Española de Ciudades de la Cerámica (AeCC)	Business association
Diakerámia	Company/business organization
ARTISAN POTIER MEMBRE DE TNSO ET DU CNC	Company/business organization
ICIM spa	Company/business organization
Freelance project leader - Nutrition, Scientific & Regulatory Affairs	Other **(no recategorization)**
MARCO PASQUALINI & PARTNERS	Company/business organization

Among the 27 contributing public authorities, 11 indicated national contribution, 9 regional, 5 international, and 2 local. Among the 327 contributing organisations, the largest number of contributions come from SMEs (n=124), followed by large organizations (n=112) and micro-size organizations (n=91).

Table 9: Organization size of stakeholder contributors

Organization size	Count	Per cent
Large (250 or more)	112	34%
Medium (50 to 249 employees)	57	17%
Small (10 to 49 employees)	67	20%
Micro (1 to 9 employees)	91	28%

Regarding the geographical distribution of respondents (see Table 10), most contributions came from EU Member States (n=568, 93%). The largest groups of contributions were submitted by respondents based in France (n=131, 22%) and Germany (n=104, 17%), followed by Hungary (n=76, 12%), Belgium (n=70, 11%), Italy (n=37, 6%) and Spain (n=32, 6%). Respondents based in 18 other Member States submitted contributions to the public consultation, with no responses received from three Member States (Croatia, Cyprus and Lithuania). Responses were also submitted by respondents in third countries (n=41, 7%).

Table 10: Geographical distribution of contribution types

Country of origin	Count	Per cent
EU Member States		
France	131	22%
Germany	104	17%
Hungary	76	12%
Belgium	70	11%
Italy	37	6%
Spain	32	5%
Sweden	17	3%
Estonia	13	2%
Finland	13	2%
Denmark	13	2%

Austria	11	2%
Netherlands	9	1%
Portugal	7	1%
Czechia	7	1%
Greece	7	1%
Luxembourg	6	1%
Poland	5	1%
Romania	3	0%
Slovakia	2	0%
Malta	1	0%
Bulgaria	1	0%
Ireland	1	0%
Latvia	1	0%
Slovenia	1	0%
Third countries		
United Kingdom	12	2%
Switzerland	11	2%
United States	10	2%
Norway	3	0%
Russia	2	0%
Japan	1	0%
Total	**609**	**100%**

Analytical approach

- **Quantitative analysis of responses:** The analysis presented below is largely based on responses to closed questions related to the study's problem definition and the identification of solutions in terms of information exchange between the supply chain stakeholders and enforcement by public authorities. Prior to the reception of the answers, an analysis of the questions was performed in order to select the ones that were relevant to the current impact assessment. Cross-tabulations and other descriptive statistics were used to assess the frequency of responses and prevalence of contributors' views for each question. The relevant questions, all part of the Stakeholder question set[26] (n=327), are as follows:

Table 11: Questions considered under the present analysis

Question number	Question	Items
4b	To what extent do you agree that the following tools are appropriate for the risk management of FCM substances:	Requirement to identify substances and other information requirements
		Traceability requirements
		Mandatory registration of businesses
5	To what extent do you agree with the following:	FCM legislation should require that information relevant to sustainability is made available, e.g., energy and other resources used in production and recycling levels
9	Concerning demonstration of compliance in the FCM production chain, to what extent do you agree with the following:	The current declaration of compliance (DoC) (e.g., for plastic FCM) and requirements for information passed in the supply chain are satisfactory
		A DoC should be mandatory for all FCMs
		The DoC should be based on a fixed format with obligatory fields
		An approval step of the final FCM article will improve compliance and safety along the supply chain
		An approval step of the final FCM article will improve marketing and commercial benefits for businesses

[26] According to the European Commission website, the stakeholder part of the open public consultation questionnaire contains "Questions for businesses, representatives of businesses, consumer organisations, scientific institutions and those involved in compliance and enforcement of FCMs. The target group includes manufacturers, importers, distributors and other businesses, including SMEs, consumer and industry associations, conformity assessment bodies, non-governmental organisations, as well as Member State authorities including control bodies." (Revision of EU rules on food contact materials – Public consultation – Target audience, EC website)

		Full information on the composition of products shall at all times be easily available to competent authorities throughout the supply chain
		The supply chain should provide manufactures of final food contact materials with complete information on substances potentially migrating above 10 ppb, whether those are intentionally used or not
		Compliance information and usage indications can be made available at a batch level for intermediate FCMs
		Compliance information and usage indications should be made available on individual final articles
		The permitted use shall be clearly indicated but disclaimers disallowed
10a	To what extent do you agree that the following information should be required to pass from one business to the next in the production chain, to determine the eventual compliance of the final FCM article:	Identity of substance(s) used to manufacture FCM
		Identity of substance(s) used in the processing or conversion of FCM
		Identity of substance(s) generated adventitiously in the production process (e.g., degradation or reaction products)
		Identification of hazardous properties and/ or other toxicological information of the identified substances
		A statement that substances of a high concern (genotoxic, CMRs, EDs) are not present in the product
		Physical and chemical properties of the identified substances
		Stability and reactivity of the identified substances
		Expected migration
		Exposure data to the identified substances including from other sources besides FCM
		Restrictions or limitations of the material(s) as regards the food(s) with which it is intended to be brought into contact
		Restrictions or limitations of the material(s) as regards the time and temperature of treatment and storage in contact with the food
		Analytical testing to demonstrate the level of substances in the material
		Analytical testing to demonstrate the level of substances that may migrate into food
11	Concerning a system for transfer of information in the supply chain, to what extent do you agree with the following:	A DoC and documentation supporting compliance (supporting documentation) should be contained and transferred within a digital or electronic system as opposed to a paper-based system
		There is already a digital information exchange system such as radiofrequency identification (RFID) or machine-readable information (QR) in place in my FCM production chain (or will be in the near future) that can be used to pass safety-related information related to FCM
		Each individual FCM article should have a QR code or equivalent to give information to users of FCMs, including food businesses and consumers and to control authorities for enforcement purposes
		The system must prevent disclosure of commercially sensitive information in the supply chain, e.g., by using notified bodies/ third parties
		A centralized digital system should be established for exchange of compliance information
		A decentralized digital system should be established for exchange of compliance information
12	Concerning the roles and responsibilities of different actors, to what extent do you agree with the following:	FCM legislation should clearly identify to which actors (manufacturers of starting substances, convertors, final FCM article producers) specific rules or information requirements apply
		Notified Bodies should be used for the verification of compliance and would help businesses to ensure safety
		Notified Bodies would help businesses reduce costs of placing their products on the market in the long term, particularly for SMEs
		Member States competent authorities should carry out regular physical and documentary checks on FCMs
		Member States competent authorities should be supported by the use of delegated bodies as provided by Regulation (EU) 2017/625 for official controls

- **Qualitative analysis of responses:** The Stakeholder part of the public consultation questionnaire included an open-text question, namely question 10b, that was deemed relevant to the present impact assessment support study ("What other information should be required to pass from one business to the next in the production chain? In particular, what toxicological information should be provided for tier 3 substances?"). Moreover, 115 respondents submitted position papers to further develop their opinion on

the matter. Most of them were submitted by business associations (n=61, 53%), companies/business organizations (n=27, 23%), NGOs (n=14, 12%), public authorities (n=9, 8%), and consumer organizations (n=4, 3%), as described in Table 6. In terms of geographical distribution, 47 entities have a European range of actions (41%), while 14 organizations are based in Germany (12%), 9 respectively in France and in Sweden (8%). Others span across 15 countries including 4 third countries. The inputs provided in position papers have been used to complement the quantitative analysis in order to add some insights and views that could better explain the reasons of the quantitative results.

Table 12: Organization type of contributors having submitted a position paper

I am giving my contribution as a/an	Count	Per cent
Business association	61	53%
Company/business organization	27	23%
Non-governmental organization (NGO)	14	12%
Public authority	9	8%
Consumer organization	4	3%

Table 13: Geographical range of action of contributors having submitted a position paper

Range of action	Count	Per cent
Europe-wide	47	41%
EU Member States		
Germany	14	12%
France	9	8%
Sweden	9	8%
Spain	7	6%
Italy	4	3%
Finland	3	3%
Belgium	3	3%
Netherlands	2	2%
Portugal	2	2%
Luxembourg	1	1%
Estonia	1	1%
Denmark	1	1%
Austria	1	1%
Czechia	1	1%
Third countries		
Switzerland	4	3%
United States	4	3%
United Kingdom	1	1%
Australia	1	1%
Total	**115**	**100%**

The following sections present the key findings from the public consultation, focusing on i) the problem definition; and EU intervention on (ii) risk management tools, (iii) the information to be passed from one business to the next, (iv) a system for information exchange, (v) and roles and responsibilities of actors. This summary is not exhaustive of all participants' responses.

Results

Problem definition

Regarding the assessment of the current situation, respondents are very divided. Indeed, 140 respondents agree or strongly agree with the statement that **the current declaration of compliance (DoC) (e.g., for plastic FCM) and requirements for information passed in the supply chain are satisfactory**. 123 of

them disagree or strongly disagree, while 34 are neutral and 30 without an opinion. It is interesting to note that among the 34 NGOs, consumer and environmental organizations that have answered, 25 strongly disagree with this statement: these are the stakeholder groups whose respondents show the most dissatisfaction with the current situation.

Table 14: Concerning demonstration of compliance in the FCM production chain, to what extent do you agree with the following: "The current declaration of compliance (DoC) (e.g., for plastic FCM) and requirements for information passed in the supply chain are satisfactory"

Stakeholder type	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion /Answer	Total
Academic/research institution	1	3	5	3	2	2	**16**
Business association	15	24	9	23	2	10	**83**
Company/business organization	30	53	13	44	10	14	**164**
Consumer organization	0	0	0	2	4	0	**6**
Environmental organization	1	0	0	0	5	0	**6**
Non-governmental organization (NGO)	0	0	4	1	16	1	**22**
Other	0	0	0	0	0	1	**1**
Public authority	0	12	2	9	2	2	**27**
Trade union	1	0	1	0	0	0	**2**
Total	**48**	**92**	**34**	**82**	**41**	**30**	**327**

Position papers analysis could give us more insights into why some respondents are not satisfied with the current DoC and requirements for information. The stakeholders observe that documentation is often found "incomplete, undetailed" (Collectif National des Céramistes, the French National Collective of Ceramists), causing uncertainty about the actual composition of the materials. The incompleteness of the documentation can be explained by several factors; (i) the EU has not defined a fixed format for DoC of unharmonized materials (APPLiA – Home Appliance Europe), thus more instructions are needed, which would cause a lack of knowledge for manufacturers from outside Europe (Eurofins Consumer Product Testing, Stora Enso), (ii) in the absence of EU legislation, some Member States have developed their own legislation, without any harmonisation or recognition of the mutual recognition principle (Kemira Oyj), (iii) lack of enforcement of FCM Regulation and a lack of information of the public authorities (REZERO - Fundacio Prevencio de Residus i Consum Responsible, Waste Prevention and Responsible Consumption Foundation), (iv) lack of information for intermediate stage operators on the final use of the articles, which would be needed for them to provide the relevant data to their customers (Evonik Industries AG).

EU intervention – Risk Management tools

The questionnaire tested several ways of improving current regulation with stakeholders. First, the evaluation of the relevance of different risk management tools was raised (Question 4b). Secondly, concrete ways of ensuring compliance were assessed (Question 9). Thirdly, the precise content of the information exchange was discussed (Questions 5 and 10a). Finally, the questionnaire discussed the means of implementation and the roles of each party (Questions 11 and 12). The position papers analysis was beneficial to give explanation for the answers brought to certain items.

In terms of tools of risk management of FCM substances, the most valued proposition by the respondents is traceability requirements, as 268 (82%) of them agree (n=168) or strongly agree (n=100), while they are only nine (3%) that disagree (n=7) or strongly disagree (n=2). Requirement to identify substances and other information requirements are also highly valued from stakeholders: 244 (75%) if them agree or strongly agree with the statement, which has the highest number of "strongly agree" answers (n=124). Notably, all respondents who disagree (n=18) or strongly disagree (n=16) are companies/business organizations or business associations, representing 14% of their categories.

Mandatory registration of businesses seems to be a more debatable tool. It gathers agree (n=75) and strongly agree (n=88) answers from 163 respondents (66%), while 58 disagree or strongly disagree (23%), among which 56 are companies/business organizations or business associations, representing 23% of their categories.

Table 15: To what extent do you agree that the following tools are appropriate for the risk management of FCM substances?

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	No opinion/answer
Requirement to identify substances and other information requirements (n= 327)	124 (38%)	120 (37%)	22 (7%)	18 (6%)	16 (5%)	27 (8%)
Traceability requirements (n= 327)	100 (31%)	168 (51%)	27 (8%)	7 (2%)	2 (<1%)	23 (7%)
Mandatory registration of businesses (n= 327)	88 (27%)	75 (23%)	63 (19%)	30 (9%)	28 (9%)	43 (13%)

EU intervention – Means of demonstrating compliance

Means of demonstrating compliance have also been discussed in the open public consultation.

The answers gaining the most support from respondents are those: (i) proposing a mandatory DoC for all FCMs, with 142 respondents strongly agreeing (43%) and 119 agreeing (36%); (ii) stating that full information on the composition of products shall at all times be easily available to competent authorities throughout the supply chain, with 127 respondents strongly agreeing (39%) and 99 agreeing (30%); (iii) proposing a DoC based on a fixed format with obligatory fields, with 108 respondents strongly agreeing (33%) and 103 agreeing (31%).

The analysis of the position papers brings however some contradictory opinions about these propositions: making at all times easily available to competent authorities full information on the composition of products is considered as not needed (Verband der Mineralfarbenindustrie e.V., German Mineral Paint Industry Association). In regards with a fixed format for DoCs, some stakeholders, especially from the industry sector, worry that such a tool could not adapt to specific needs of each type of material, food, or sector (Grow International, Braskem, Evonik, AkzoNobel, Flexible Packaging Europe, European Enamel Association), or that it could not be possible to distinguish companies with a performant process anymore (Ammega).

Four propositions gather more nuanced answers from respondents: (i) The proposition that supply chain should provide manufactures of final food contact materials with complete information on substances potentially migrating above 10 ppb, whether those are intentionally used or not, is strongly agreed (n=105) or agreed (n=86) by 58% of respondents, while 19% of them disagree (n=34) or strongly disagree (n=41). In their position papers, stakeholders claim that feasibility is questionable since it would lead to a considerable amount of tests (Fritz Egger GmbH., Plastics Europe), and because substance migration depends on how the product is used by the downstream manufacturer user, which is an information the upstream manufacturer does not have (Kemira Oyj, EFCEM – European Federation of Catering Equipment Manufacturers, TDMA – Titanium Dioxide Manufacturers Association). Consequently, stakeholders judge that this measure would not provide any added value in terms of safety (Plastics Europe, Normpack).

(ii) Compliance information and usage indications should be made available on individual final articles receives the strong agreement (n=69) or agreement (n=89) of 48% of respondents, while 24% disagree (n=39) or strongly disagree (n=41). Stakeholders who disagree claim that it would not be feasible due to the amount of information to include (Swedish Forest Industries Federation, Sherwin-Williams) and the variety of use of final articles (Swedish Forest Industries Federation). It would also not give any added value to the customer because compliance information is highly technical (APPLiA – Home Appliance Europe).

(iii) The permitted use shall be clearly indicated but disclaimers disallowed, sees the respondents very divided. 107 (33%) strongly agree (n=53) or agree (n=54) with the proposition, while 111 (34%) strongly disagree (n=49) or disagree (n=62). 109 (33%) have no opinion (n=71) or are neutral (n=38). FEFCO (European Federation of Corrugated Board Manufacturers) claims in its position paper that "disallowing disclaimers would restrict the possible uses of FCMs and increase food waste. The final article producer does not have a control over the use and all the information about the potential use, which makes the use of disclaimers absolutely necessary to prevent potential misuse and ensure appropriate responsibility in the supply chain."

(iv) Compliance information and usage indications can be made available at a batch level for intermediate FCMs receives the strong agreement (n=30) or agreement (n=80) from 34% of the respondents. 114 of them (34%) disagree (n=39) or strongly disagree (n=75), among which 46% of business associations and companies/business organisations. 31% (n=103) are neutral (n=61) or without an opinion (n=42). Stakeholders make the claim that such measure would be an unnecessary administrative burden, and a waste of their resources (Alliance for Beverage Cartons and the Environment, Flexible Packaging Europe, Normpack). Alliance for Beverage Cartons and the Environment adds that this proposition is "contradictory

with the 'family approach' and the 'building block concept' that are already being used and provide a more sustainable and practical way of ensuring the safety of a product."

Finally, two statements are particularly disagreed with: (i) an approval step of the final FCM article will improve compliance and safety along the supply chain receives 136 answers (42%) showing disagreement (n=66) or strong disagreement (n=70). 51% of the companies/business organizations and business associations having responded disagree (n=58) or strongly disagree (n=69). However, 68% of the other stakeholder groups respondents agree (n= 41) or strongly agree (n=13). (ii) A similar observation can be made on the proposition 'An approval step of the final FCM article will improve marketing and commercial benefits for businesses'. 46 respondents (14%) agree (n=27) or strongly agree (n=19), while 42% do not have an opinion (n=80) or are neutral (n=38). 44% strongly disagree (n=96) or disagree (n=47). For those two propositions, stakeholders fear that it would affect efficiency in product development (EuroCommerce). The French National Ceramists Collective disagree with shifting proof of conformity on the final product. All craft ceramic products being unique, the entire production should be analyzed in a laboratory, which is not feasible: ceramists would face an important financial constraint, and the items subject to laboratory tests would need to be destroyed.

Table 16: Concerning demonstration of compliance in the FCM production chain, to what extent do you agree with the following:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion/Answer
A Declaration of Compliance (DoC) should be mandatory for all Food Contact Materials (FCMs)	142 (43%)	119 (36%)	20 (6%)	16 (5%)	9 (3%)	21 (6%)
The DoC should be based on a fixed format with obligatory fields	108 (33%)	103 (31%)	42 (13%)	29 (9%)	23 (7%)	22 (7%)
An approval step of the final FCM article will improve compliance and safety along the supply chain	37 (11%)	66 (20%)	54 (17%)	66 (20%)	70 (21%)	34 (10%)
An approval step of the final FCM article will improve marketing and commercial benefits for businesses	19 (6%)	27 (8%)	58 (18%)	47 (14%)	96 (29%)	80 (24%)
Full information on the composition of products shall at all times be easily available to competent authorities throughout the supply chain	127 (39%)	99 (30%)	34 (10%)	30 (9%)	13 (4%)	24 (7%)
The supply chain should provide manufactures of final food contact materials with complete information on substances potentially migrating above 10 ppb, whether those are intentionally used or not	105 (32%)	86 (26%)	30 (9%)	31 (9%)	34 (10%)	41 (13%)
Compliance information and usage indications can be made available at a batch level for intermediate FCMs	30 (9%)	80 (24%)	61 (19%)	39 (12%)	75 (23%)	42 (13%)
Compliance information and usage indications should be made available on individual final articles	69 (21%)	89 (27%)	44 (13%)	39 (12%)	41 (13%)	45 (14%)
The permitted use shall be clearly indicated but disclaimers disallowed	53 (16%)	54 (17%)	38 (12%)	62 (19%)	49 (15%)	71 (22%)

EU intervention – Information to pass from one business to the next in the production chain

The open public consultation (Question 10a) has also tested with the stakeholders in a more precise way the required information to pass from one business to the next in the production chain.

Three items gather a strong consensus from stakeholders, the first two being related to conditions of use: (i) Restrictions or limitations of the material(s) as regards the food(s) with which it is intended to be brought into contact has the agreement (n=97) or strong agreement (n= 155) of 76% of respondents. (ii) Restrictions or limitations of the material(s) as regards the time and temperature of treatment and storage in contact with the food receives the agreement (n=108) or strong agreement (n= 153) of 79% of respondents. Stakeholders point out that information related to conditions of use should not be passed for intermediate material (Evonik Industries AG, Normpack). (iii) Finally, respondents show a strong support for passing the identification of hazardous properties and/or other toxicological information of the identified substances: 234 strongly agree or agree (71%). However, 35 companies/business organizations or business associations disagree or strongly disagree, representing 14% of this stakeholder type. For hazardous

substances, stakeholders clarify that such data is already exchanged through safety data sheets, public databases or other reliable sources such as ECHA (Kemira Oyj, Venator, CEPE).

Six proposals received a rather favourable opinion from the participants:

(i) Identity of substance(s) used to manufacture FCM has support from 68% of the respondents, 132 strongly agreeing and 93 agreeing. Notably, 25% (n=61) of companies/business organizations or business associations having responded disagree (n=36) or strongly disagree (n=28). (ii) The related item "identity of substance(s) used in the processing or conversion of FCM" gathers less support, as 56% of respondents strongly agree (n=98) or agree (n=91). Likewise, 33% (n=82) of companies/business organizations or business associations having responded disagree (n=49) or strongly disagree (n=38). (iii) Identity of substance(s) generated adventitiously in the production process (e.g. degradation or reaction products) shows similar results: 51% of the respondents strongly agree (n=86) or agree (n=80) with the requirement of passing this information. 24% are neutral (n=47) or do not have an opinion (n=30). 84 disagree (n=54) or strongly disagree (n=30) with the statement, among which 32% of companies/business organizations or business associations having responded (n=80). These requirements are disagreed with for various reasons, among which the fact that it would not be suitable and not lead to a higher degree of safety (Normpack), and that this information would be commercially sensitive (CEPE - European Council of the Paint, Printing Ink and Artists Colours Industry, Silicones Europe, Swedish Forest Industries Federation). However, some stakeholders agree that transfer of information regarding substances identity should be limited to substances with migration potential (Verband der Mineralfarbenindustrie e.V., Normpack). For the specific matter of non-intentionally added substances (NIAS), stakeholders point out that methodological gaps exist (ADEPALE). In regards with "identity of substance(s) generated adventitiously in the production process" a stakeholder says that this information would not be useful to pass on as these substances are cleaned up during the manufacture process (SYNEG).

(iv) Requiring a statement that substances of a high concern (genotoxic, CMRs, EDs) are not present in the product is supported by 51% of respondents as well, with 86 strongly agreeing and 82 agreeing. 18% are neutral (n=33) or do not have an opinion (n=27). 99 disagree (n=62) or strongly disagree (n=37) with the statement, among which 36% of companies/business organizations or business associations having responded (n=90). One reason for disagreeing is that saying that any substance is not present is analytically impossible to demonstrate (CEPE - European Council of the Paint, Printing Ink and Artists Colours Industry).

Lastly, two statements related to migrating products have received a rather favourable opinion as well: (v) Requiring passing from one business to another the expected migrations gains support from 59% of the respondents, 104 strongly agreeing and 90 agreeing. 69 respondents (21%) still disagree (n=46) or strongly disagree (n=23), among which 26% of companies/business organizations or business associations having responded (n=65). (vi) Analytical testing to demonstrate the level of substances that may migrate into food shows slightly milder results. 54% of respondents strongly agree (n=102) or agree (n=74) with this requirement. A less important number of respondents strongly disagree (n=22) or disagree (n=49), but the share of companies/business organizations or business associations having responded that strongly disagree (n=22) or disagree (n=46) is up to 28%. For some stakeholders, it should be taken into consideration that upstream migration results are not transposable to final products (Francéclat), and that the transmission of the full test reports is not viable (Finnish Forest Industries Federation). Moreover, a stakeholder points out that it should be mandatory only when there is no positive list (SYNEG).

Two statements show more mixed results. (i) Analytical testing to demonstrate the level of substances in the material (migrating and not migrating substances alike) has support of 40% of the respondents(n=130), 74 strongly agreeing and 56 agreeing; 27% are neutral (n=57) or do not have an opinion (n=32); and 33% disagree (n=77) or strongly disagree (n=31). 41% of companies/business organizations or business associations having responded strongly disagree (n=30) or disagree (n=72). In regards with analytical testing, some stakeholders specify that (ii) Stability and reactivity of the identified substances is supported by 31% of respondents, 41 strongly agreeing and 62 agreeing, while 33% are neutral (n=70) or without an opinion (n=38). 35% do not support this statement (n=116), with 72 respondents disagreeing and 44 strongly disagreeing. As in the previous proposal, an important share (45%) of companies/business organizations or business associations having responded strongly disagree (n=44) or disagree (n=67). Just as hazardous substances, stability data is "normally exchanged through the means of safety data sheet" and should not be part of DoC (Venator).

Finally, the last two statements received a rather unfavourable opinion from the respondents.

(i) 38% of respondents (n=125) do not support that exposure data to the identified substances including from other sources besides FCM should be a required information to pass from one business to the other. Only 30% of respondents strongly agree (n=37) or agree (n=60) with the statement, while 32% are neutral (n=62) or do not have an opinion (n=43). (ii) The statement "Physical and chemical properties of the identified substances" shows similar results, with 29% of respondents strongly agreeing (n=40) or agreeing

(n=56), while 41% showed no support, with 74 respondents disagreeing and 59 strongly disagreeing. 50% of companies/business organizations or business associations having responded strongly disagree (n=58) or disagree (n=66). Stakeholders point out that this kind of data is already exchanged through safety data sheets (Venator), is already "accessible in public databases and in SDS" (Kemira Oyj), or has no utility for the final user (SYNEG).

However, the type of information that has the least support from respondents can be found in the response items of question 5 (see Table 12): "To what extent do you agree with the following: FCM legislation should require that information relevant to sustainability is made available, e.g. energy and other resources used in production and recycling levels". 50% disagree (n=90) or strongly disagree (n=73) with the statement. 61% of the companies/business organizations or business associations have responded they strongly disagree (n=70) or disagree (n=80). 26% of the respondents (n=84) support the idea, and 24% are neutral (n=57) or do not have an opinion (n=23). This result is in line with the statements made in the position papers: stakeholders would not be favourable to measures going beyond the scope of the FCM Regulation, as such topics are already covered by other Regulations (EuroCommerce, Agence Fédérale pour la Sécurité de la Chaîne Alimentaire, EUROPEN, Flexible Packaging Europe, Swedish Forest Industries Federation).

Table 17: To what extent do you agree that the following information should be required to pass from one business to the next in the production chain, to determine the eventual compliance of the final FCM article:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion/Answer
Identity of substance(s) used to manufacture FCM	132 (40%)	93 (28%)	21 (6%)	36 (11%)	28 (8%)	17 (5%)
Identity of substance(s) used in the processing or conversion of FCM	98 (29%)	91 (27%)	32 (9%)	49 (14%)	38 (11%)	19 (5%)
Identity of substance(s) generated adventitiously in the production process (e.g. degradation or reaction products)	86 (26%)	80 (24%)	47 (14%)	54 (16%)	30 (9%)	30 (9%)
Identification of hazardous properties and/ or other toxicological information of the identified substances	106 (32%)	128 (39%)	30 (9%)	22 (6%)	15 (4%)	26 (7%)
A statement that substances of a high concern (genotoxic, CMRs, EDs) are not present in the product	86 (26%)	82 (25%)	33 (10%)	62 (18%)	37 (11%)	27 (8%)
Physical and chemical properties of the identified substances	40 (12%)	56 (17%)	65 (19%)	74 (22%)	59 (18%)	33 (10%)
Stability and reactivity of the identified substances	41 (12%)	62 (18%)	70 (21%)	72 (22%)	44 (13%)	38 (11%)
Expected migration	104 (31%)	90 (27%)	33 (10%)	46 (14%)	23 (7%)	31 (9%)
Exposure data to the identified substances including from other sources besides FCM	37 (11%)	60 (18%)	62 (18%)	68 (20%)	57 (17%)	43 (13%)
Restrictions or limitations of the material(s) as regards the food(s) with which it is intended to be brought into contact	155 (47%)	97 (29%)	38 (11%)	13 (3%)	5 (1%)	19 (5%)
Restrictions or limitations of the material(s) as regards the time and temperature of treatment and storage in contact with the food	153 (46%)	108 (33%)	29 (8%)	9 (2%)	6 (1%)	22 (6%)
Analytical testing to demonstrate the level of substances in the material	74 (22%)	56 (17%)	57 (17%)	77 (23%)	31 (9%)	32 (9%)
Analytical testing to demonstrate the level of substances that may migrate into food	102 (31%)	74 (22%)	50 (15%)	49 (14%)	22 (6%)	30 (9%)

Table 18: To what extent do you agree with the following: FCM legislation should require that information relevant to sustainability is made available, e.g. energy and other resources used in production and recycling levels:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion/Answer
Identity of substance(s) used to manufacture FCM	32 (10%)	52 (16%)	57 (17%)	90 (28%)	73 (22%)	23 (7%)

EU intervention – System for transfer of information

When testing the agreement of stakeholders towards the establishment of a system for information transfer in the FCM supply chain, the following proposals were most valued by stakeholders. Most respondents (n=205, 63%) agreed with the proposal of a digital or electronic system to contain and transfer supporting compliance documentation as opposed to a paper-based system, whereas 36 respondents (11%) disagreed (n=26) or strongly disagreed (n=10). This proposal was supported in several of the position papers submitted with the OPC. In particular, stakeholders highlighted the following elements: (i) the exchange of digital information would help businesses and SMEs to ensure compliance (Confederation of European Paper Industries, EEA - European Enamel Association AISBL), increase the possibility of actors in the supply chain to get more detailed and up-to-date information, including the possibility to provide additional information to what is required by the EU legislation (Amazon), but it would also be beneficial to facilitate the work of competent authorities (Verbraucherzentrale Bundesverband e.V.), (ii) the sharing of digital information on raw materials would make it easier for professionals to choose the right materials for their FCM articles (National Ceramists' Collective), (iii) it could improve accountability, information flow and compliance work for both the industry and competent authorities (The Finnish Forest Industries Federation, Swedish Chemicals Agency, Stora Enso). In their position papers, stakeholders have provided the following recommendations: (i) paper-based documentation should be maintained in case of electronic malfunction of the system, (ii) the setup of the system should take into account the added costs for compliance and management, (iii) the setup of such a system should be easy and practical to use for all parties involved (Eurocolor e.V., Verband der Mineralfarbenindustrie e.V.), and more user-friendly than similar systems already in use e.g., REACH registration (Normpack, Venator). Other stakeholders have recommended that the system should be structured as a data repository accessible to enforcement authorities (Plastics Europe), (iv) a consistent approach must be ensured with other regulatory frameworks envisaging digital means of providing information (UNESDA Soft Drinks Europe), (v) support should be provided to industry and especially SMEs to transition to digitalization (FEC). Those who have opposed such a digital system claimed that (i) the imposition of one large and complex IT system would be very expensive and would not deliver the ease of use that is essential to ensure proper uptake at all levels including SMEs (Metal Packaging Europe), (ii) a completely digitalized system for sharing compliance information would be vulnerable and the level of IT maturity in different countries would vary, therefore such system would need to still allow contributions through uploading information in pdf format (Normpack).

There was large agreement among contributors (n= 173, 53%) about the need for the proposed digital or electronic system to prevent disclosure of commercially sensitive information in the supply chain (e.g., by using notified bodies/third parties), as opposed to 60 respondents (18%) who disagreed (n=27) or strongly disagreed (n=33). In their position papers, stakeholders have highlighted that the system should (i) respect confidentiality of information (The Finnish Forest Industries Federation, Stora Enso, TotalEnergies Corbion, CEPE, EEA - European Enamel Association AISBL, EuPIA), in particular of supporting documentation that should remain confidential (Tetra Pak, The Alliance for Beverage Cartons and the Environment). Some of them expressed concerns regarding the protection of sensitive data in such a system (Henkel AG & CO KGaA), others claimed that any attempt to make business operators disclose information on substances could disadvantage European producers and lead to a relocation of production outside the EU where confidential information is protected (Verband der Mineralfarbenindustrie e.V.). Manufacturers in fact would not want to reveal the identity of the substances used, unless there is potential for migration (UNESDA Soft Drinks Europe). Some stakeholders strongly disagreed with the use of notified bodies to prevent the disclosure of commercially sensitive information in the supply chain (CEPE, EEA - European Enamel Association AISBL, The Finnish Forest Industries Federation, Flint Group, Federchimica), which would imply large costs for business operators and longer procedures affecting time to market (EEA - European Enamel Association AISBL, The Alliance for Beverage Cartons and the Environment), whereas other stakeholders support relying mainly on non-disclosure agreements to ensure confidentiality in the sharing of business information (EuPIA).

Concerning the governance of the proposed digital and electronic system, respondents to the OPC generally tended to favor the establishment of a centralized digital system to exchange compliance information, which was supported by more respondents (n=143, 44%), as opposed to 86 of them (26%) who either disagreed (n=46) or strongly disagreed (n=40). This finding is corroborated by the fact that, on the other hand, more respondents (n=129, 39%) did not agree with the establishment of a decentralized digital system for the exchange of compliance information, whereas only 48 respondents (15%) agreed (n=34) or strongly agreed (n=14). Among the stakeholders that have submitted position papers, the following have expressed a preference for a centralized system for information exchange: Cefic, Swedish Food Federation, Swedish Forest Industries Federation, Venator, Collectif National des Céramistes, TÜV Rheinland AG, European Carton Makers Association - ECMA. Others opposed a centralized system (ADEPALE) claiming that the platform for

sharing content of DoCs should be decentralized and under the control of individual manufacturers as in the process foreseen by DG GROW for the Sustainable Product Initiative (Mitsubishi Chemical Europe GmbH).

Most contributors (n=132, 40%) either did not confirm or had no opinion (n=119, 36%) on the existence of a digital information exchange system in place for the FCM production chain to be used to pass on safety-related information. More respondents tended to either disagree (n=137, 42%) or be neutral (n=74, 23%) with regards to the proposal of placing a QR code or equivalent on FCM articles providing information to businesses, authorities and consumers. In the position papers, some stakeholders were convinced that the information passed through the QR system should not be made available to consumers as presenting this information to them might instil doubt instead of a feeling of safety as to whether the packaging is safe to use or not (Citeo). Others have questioned the relevance of having the same information in a QR code for authorities, business operators and consumers when all of them have different information needs (Swedish Food Federation), as well as challenges with sharing safety information with a tool that is meant for traceability of the products' name and bath numbers (Mitsubishi Chemical Europe GmbH). Some consumer organizations called for QR codes to complement information that is directly shown on products so that consumers can have access to it also offline (Forbrugerrådet Tænk (Danish Consumer Council)), whereas other actors underlined the foreseeable difficulties that SMEs may face when implementing a system of QR codes on FCM (Plastics Europe).

Several position papers have discussed about digital labelling products vis-à-vis on-product labelling as primary mean of communicating information on FCM to consumers. Stakeholders have highlighted the importance of communicating about the full composition of FCM not only to authorities but also to consumers (Forbrugerrådet Tænk (Danish Consumer Council), Papacks Green Holding). Some stakeholders have claimed that digital labelling would however risk undermining informed consumer choice as it would make the access to information more time consuming and burdensome or exclude some consumers from essential information (Food and Veterinary Office of the Canton St. Gallen, Générations Futures). For the same reason, others have recommended that digital labelling is used as a complement to physical labels (BEUC - The European Consumer Organisation). As a solution, stakeholders have proposed that labelling may be an information document which is separate from the product and does not appear inseparably on it (Cerame-Unie). Some have mentioned that a point of departure for a digital labelling for FCM should be the EU Ecolabel (Swedish Forest Industries Federation, Papacks Green Holding).

Table 19: Concerning a system for transfer of information in the supply chain, to what extent do you agree with the following:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion/Answer
A DoC and documentation supporting compliance (supporting documentation) should be contained and transferred within a digital or electronic system as opposed to a paper-based system (n= 327)	70 (21%)	135 (41%)	60 (18%)	26 (8%)	10 (3%)	26 (8%)
There is already a digital information exchange system such as radiofrequency identification (RFID) or machine-readable information (QR) in place in my FCM production chain (or will be in the near future) that can be used to pass safety-related information related to FCM (n= 327)	9 (3%)	29 (9%)	38 (12%)	82 (25%)	50 (15%)	119 (36%)
Each individual FCM article should have a QR code or equivalent to give information to users of FCMs, including food businesses and consumers and to control authorities for enforcement purposes (n= 327)	28 (9%)	43 (13%)	74 (23%)	80 (24%)	57 (17%)	45 (14%)
The system must prevent disclosure of commercially sensitive information in the supply chain, e.g., by using notified bodies/ third parties (n= 327)	64 (20%)	109 (33%)	49 (15%)	27 (8%)	33 (10%)	45 (14%)
A centralized digital system should be established for exchange of compliance information (n= 327)	47 (14%)	96 (29%)	53 (16%)	46 (14%)	40 (12%)	45 (14%)
A decentralized digital system should be established for exchange of compliance information (n=327)	14 (4%)	34 (10%)	97 (30%)	83 (25%)	46 (14%)	53 (16%)

EU intervention – Roles and responsibilities in the FCM supply chain

In terms of roles and responsibilities of different actors in the FCM supply chain, most contributors (n=303, 93%) agreed (n=128) or strongly agreed (n=175) with the need for the FCM legislation to specify to which actors specific rules of information requirements apply. In their position papers, some stakeholders claimed that information on product composition only needs to be made available to relevant specific individual actors in the supply chain (UNESDA Soft Drinks Europe) or even exclusively to national or European authorities (TotalEnergies Corbion, The Alliance for Beverage Cartons and the Environment), whereas others sustained that all actors should have access to such information (Swedish Chemicals Agency), in particular that on the content of hazardous substances in FCM (CHEM Trust), (iii) the need for manufacturers outside of the EU to be instructed on how to comply with European safety requirements and be integrated in any digital tool for information exchange (Eurofins Consumer Product Testing).

There was equally large agreement on the fact that Member States' competent authorities should carry out regular physical and documentary checks on FCMs (n=239, 73%). More respondents (n=133, 41%) tended to either agree (n=88) or strongly agree (n=45) with the use of delegated bodies to support Member States' competent authorities during official controls as provided by Regulation 2017/625, compared to those (n=57, 17%) that disagreed (n=23) or strongly disagreed (n=34). Respondents were divided when it comes to the use of notified bodies for the verification of compliance and on whether they could be helpful to businesses to ensure safety, with 129 respondents (39%) agreeing (n=90) or strongly agreeing (n=39) with this statement and 122 respondents (37%) disagreeing (n=43) or strongly disagreeing (n=79) with it. In addition, more contributors (n=130, 40%) tended to reject the idea that notified bodies would help businesses reduce costs of placing their products on the market in the long term, compared to those (n=75, 23%) that agreed (n=45) or strongly agreed (n=30) with this statement. In the position papers, some stakeholder disagreed with the involvement of notified and delegated bodies for official controls or the verification of compliance, as this would (i) increase bureaucracy and administrative burden and potentially create bottleneck to putting products on the market (The Alliance for Beverage Cartons and the Environment) and (ii) notified bodies would not be helpful to businesses to reduce costs (EFCEM European Federation of Catering Equipment Manufacturers). Others proposed that the use of notified and delegated bodies is available to Member State authorities, however on a voluntary basis (FoodDrinkEurope).

Table 20: Concerning the roles and responsibilities of different actors, to what extent do you agree with the following:

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion/Answer
FCM legislation should clearly identify to which actors (manufacturers of starting substances, convertors, final FCM article producers) specific rules or information requirements apply (n= 327)	175 (54%)	128 (39%)	8 (2%)	3 (1%)	1 (0%)	12 (4%)
Notified Bodies should be used for the verification of compliance and would help businesses to ensure safety (n= 327)	39 (12%)	90 (28%)	42 (13%)	43 (13%)	79 (24%)	34 (10%)
Notified Bodies would help businesses reduce costs of placing their products on the market in the long term, particularly for SMEs (n= 327)	30 (9%)	45 (14%)	40 (12%)	54 (17%)	76 (23%)	82 (25%)
Member States competent authorities should carry out regular physical and documentary checks on FCMs (n= 327)	110 (34%)	129 (39%)	59 (18%)	6 (2%)	3 (1%)	20 (6%)
Member States competent authorities should be supported by the use of delegated bodies as provided by Regulation (EU) 2017/625 for official controls (n= 327)	45 (14%)	88 (27%)	89 (27%)	23 (7%)	34 (10%)	48 (15%)

Questionnaire template

Interview guides

List of sources

6. Industry Case Studies

6.1. Plastic Industry

6.1.1. Introduction to the plastics industry

The EU is one of the world's largest producers and consumers of plastics, with a robust and well-established industry. The EU plastics industry encompasses a wide range of activities, including the production of raw materials (polymers and additives), plastic processing and manufacturing of plastic products. Plastics are widely used for FCM due to their versatility, durability, and cost-effectiveness. Plastics for FCM purposes includes the following applications, among others:

- Packaging of food products, in various formats: plastic bags, plastic wraps, and plastic containers. Plastic packaging helps protect food from contamination, extends shelf life, and provides convenient storage and transportation options.
- Bottles and containers are prevalent in the food and beverage industry for packaging liquids and solids. PET (polyethylene terephthalate) is commonly used for beverage bottles, while HDPE (high-density polyethylene) and PP (polypropylene) are used for various food containers.
- Food trays and clamshells are used for packaging fresh produce, bakery items, and takeout meals. They offer transparency, allowing consumers to view the product inside.

6.1.2. Functioning of the plastics supply chain

The supply chain of plastics for FCM begins with the production of raw materials for plastics, such as petrochemicals, which serve as the basis for plastic resin production. Raw materials are usually globally sources; however, they must meet EU safety and quality standards when being imported for processing in the EU. Such resins are produced through polymerization processes to create specific types of plastic suitable for food contact applications, such as polyethylene (PE), polypropylene (PP), or polyethylene terephthalate (PET). Polymer resins are often blended with additives to enhance their properties, such as stability, color, or UV resistance. Compounding facilities in the EU mix the resin and additives to create customized materials that meet specific requirements for FCM. These compounded resins are then used by manufacturers in the EU to produce various plastic products for food contact applications, including packaging materials, containers, trays, films, and more. Manufacturing processes, such as injection molding, extrusion, and thermoforming, are employed to shape plastics into the desired forms. Throughout this process, strict quality control measures and testing ensure compliance with the EU FCM legislation, including specific migration limits and authorized substances. Extensive documentation, including DoC, traceability systems, and records, is maintained to uphold transparency and accountability. Once verified for compliance, FCM plastics are distributed to packaging companies and end-users, ensuring the integrity of food products during storage and transportation. The entire supply chain is monitored and enforced by regulatory authorities in EU Member States to guarantee that plastics used for food contact applications are safe and meet rigorous standards, thus safeguarding consumer health and well-being. At the end of their life, plastics FCMs can enter the recycling process. Once collected, these plastics undergo a meticulous process that includes sorting, cleaning, and processing. Depending on the method employed, the plastics may be mechanically recycled, where they are melted and re-molded into new food contact materials, or chemically recycled, where they are broken down into their constituent monomers for reuse. Plastics that cannot be recycled are disposed of in accordance with EU waste management regulations, either through incineration or landfill.

6.1.3. Regulation of plastics FCM

Plastics is a "harmonized material", which means that the FCM legislation establishes harmonized rules applying across the EU to make sure that plastics materials do not transfer their constitutes to food in quantities that could endanger human health or change the food composition, odor or taste. The legislation sets specific migration limits for certain substances used in plastics detailing the maximum allowable transfer of substances from plastics into food. There is a positive list of substances that plastics used in FCM can contain and that are explicitly listed as authorized for such use, as well as their maximum limit. Producers of plastics for FCM are bound to ensure that their products comply with safety requirements. To this end, they have to perform safety evaluations and risk assessments, taking into account the intended use of the plastics and foreseeable contact conditions. They also need to adhere to Good Manufacturing Practices to ensure safety and quality of their products (proper hygiene, traceability, documentation of material and production processes). Manufacturers and importers of plastics FCM must provide a Declaration of

Compliance (DoC) for their products, which confirms that the materials and articles meet regulatory requirements and include information on the composition of the material, any restrictions on its use and relevant test data. Traceability needs to be ensured by business operators, who must establish and maintain records to trace the origin of their materials and products for safety and compliance.

6.1.4. Information exchange in the plastics supply chain

Manufacturers of plastic resins provide detailed material specifications, including the resin's composition, additives used, and relevant technical data to their customers. In particular, downstream business operators would receive TDS (information on typical property values, typical applications and information on storage and handling) and SDS (information on possible hazards, response and prevention – safe handling). These specifications serve as a foundation for assessing the suitability of the material for food contact. Manufacturers and suppliers within the supply chain may issue Declarations of Compliance (DoCs) confirming that their materials or products comply with EU FCM regulations. DoCs contain critical information, including identity and address of the business operator, date of declaration, identity of substances with a restriction 5SML or QM) in Annex I and/or II or for which genotoxicity cannot be ruled out (Annex IV-6)) and the use of so called Dual-Use additives. Additional information requirements are detailed for each business operator in Chapter 4 of the Union Guidance on Regulation No 10/2011 . DoCs serve as a formal declaration of adherence to safety and regulatory standards and contain critical information for downstream business operators to perform their own compliance work and comply with their legal duties. For plastics, the format of the DoC is provided by the FCM legislation. If the recipe changes, or if there is a change in technology, in purity of used substances or a new update to the legislation that led to a new or more strict restrictions of the material, a new DoC has to be issued. In case of less stringent or no restriction of the material, a new DoC is recommended.

In turn, plastics FCM operators communicate their specific needs and requirements to suppliers and manufacturers, such as the type of plastics required and any special considerations for their intended use. The latter is a critical information for manufactures and suppliers to perform their own risk assessments. Establishing traceability systems is equally critical for tracking the source and history of materials and products in the supply chain and help quickly identify the origin of any non-compliance issues and facilitate corrective actions.

Independent testing laboratories play a crucial role in assessing compliance and safety and in ensuring confidentiality of information related to e.g., the composition of resins and may be contracted by manufacturers, suppliers or other business operators in the supply chain. They conduct a battery of tests on plastic materials and articles to evaluate their performance against specific regulatory requirements. These tests often encompass migration limits, mechanical properties, and safety standards. Test reports generated by these laboratories provide valuable data that confirm the safety and compliance of the materials. In some cases, certain materials or products may obtain reports from recognized third-party organizations, which then serve as external validation of the material's safety and quality, adding an extra layer of assurance for stakeholders in the supply chain. Such reports may be exchanged with other actors of the supply chain to provide assurance of the quality and safety of the material without having to disclose the recipe.

Manufacturers, suppliers, and end-users may be required to report compliance information directly to regulatory authorities of National Competent Authorities (NCAs) in EU Member States. During inspections, authorities may request access, on-site or via email, to Declarations of Compliance (DoCs) containing detailed information about the material's suitability for food contact, including test results and authorized substances, as well as supporting documentation. The latter are not intended to be passed along the supply chain but should be made available to competent authorities on request. They may include (i) information on the composition of plastics materials and articles, their intended use (e.g., temperature resistance and barrier properties), (ii) safety data sheets in accordance with REACH, providing information on the hazardous properties of chemicals used in the materials, (iii) results of various tests conducted on the materials or articles to assess their compliance with specific regulatory requirements (migration testing, mechanical testing, and analytical testing for the presence of hazardous substances, risk assessments of NIAS), (iv) records detailing the origin of raw materials and components used in the FCM, as well as the production process, including dates and batch numbers, (v) records demonstrating adherence to Good Manufacturing Practices (GMP), (vi) information regarding the supply chain, including the names and contact details of all actors involved, (vii) copies of reports or assessments conducted by recognized third-party organizations that verify compliance with safety and quality standards, as well as their contact details.

6.1.5. Use case for the plastics FCM industry

Application of Policy Option 1 for information exchange and verification of compliance in the plastics supply chain

In this policy option, a centralized IT system is put in place with an EU body responsible for management and decision-making. In this configuration, the IT system consists of a centralized EU online platform connected to a central database for input and withdrawal of information.

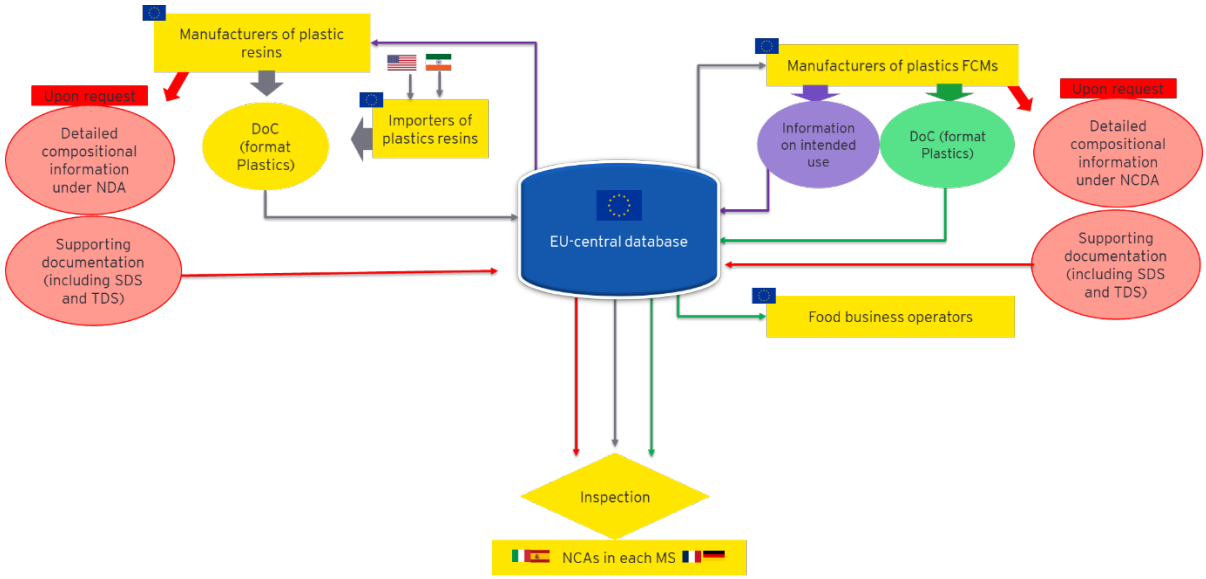
The figure exemplifies how a centralized IT system, with a singular database primarily in use, would function for the case of the plastics industry.

In this supply chain, suppliers of plastics resins submit their compliance documents (DoCs) into the IT system. For plastics, a template exists in the FCM legislation, which would allow to directly have such template in the IT systems for actors to fill in. Upon request from competent authorities, suppliers can share information under NDA or additional supporting documentation (SD – including SDS and TDS). These pieces of information shall be propagated within the IT system and managed via an access authorization system (in the case of PO1, managed by the EU body responsible for decision making on the system) to make sure that only competent authorities have access to them. As for actors from non-member countries, they conventionally utilize importers or have branches in a member state. Therefore, the onus lies upon them to feed the appropriate DoCs into the database.

Manufacturers of plastics FCMs, on the other hand, can access their suppliers' DoCs via the platform, while concurrently providing their DoCs to subsequent users (e.g., Food business operators). Again, a template exists for such DoC, which can be directly implemented in the IT system. The platform will facilitate entries for them to relay information to their suppliers about the use of their materials and to receive feedback from subsequent users about the utilization of their plastic FCMs. Similarly, they will be able to disseminate information under NDA and supporting documentation to competent authorities, depending on their request. This would be done through the same information access authorization system to ensure it only reaches the appropriate authority.

From their side, the competent authorities in the member states will have the ability to access information at any time - be it before, during, or after inspections to extract necessary information for said inspections, including all necessary supporting documentation. Finally, the database could also serve as an official communication channel for interactions between authorities and supply chain actors, in case additional information is required.

Figure 39 Application of Policy Option1 - Centralized IT system at EU level to the plastics FCM supply chain



Application of Policy Option 2 for information exchange and verification of compliance in the can-making supply chain

In this policy option, a decentralized IT system is put in place with each Member State responsible for management and decision-making. In this configuration, the IT system consists of decentralized national online platforms connected to national databases for input and withdrawal of information. National databases are made interoperable either through an EU-Hub or through interlinks between databases.

The subsequent two figures illustrate how a decentralized IT system, with several national databases, would function for the case of the plastics industry. In essence, the mode of information exchange and data gathering remains largely the same as for PO1, however the control and oversight of the system is now decentralized and relies on an interconnected web of national databases as explained for the case of the metal packaging industry.

Figure 40 Application of Policy Option 2 - Decentralized IT System at Member State level to the plastics FCM supply chain (Option with an EU Hub for interoperability of national databases)

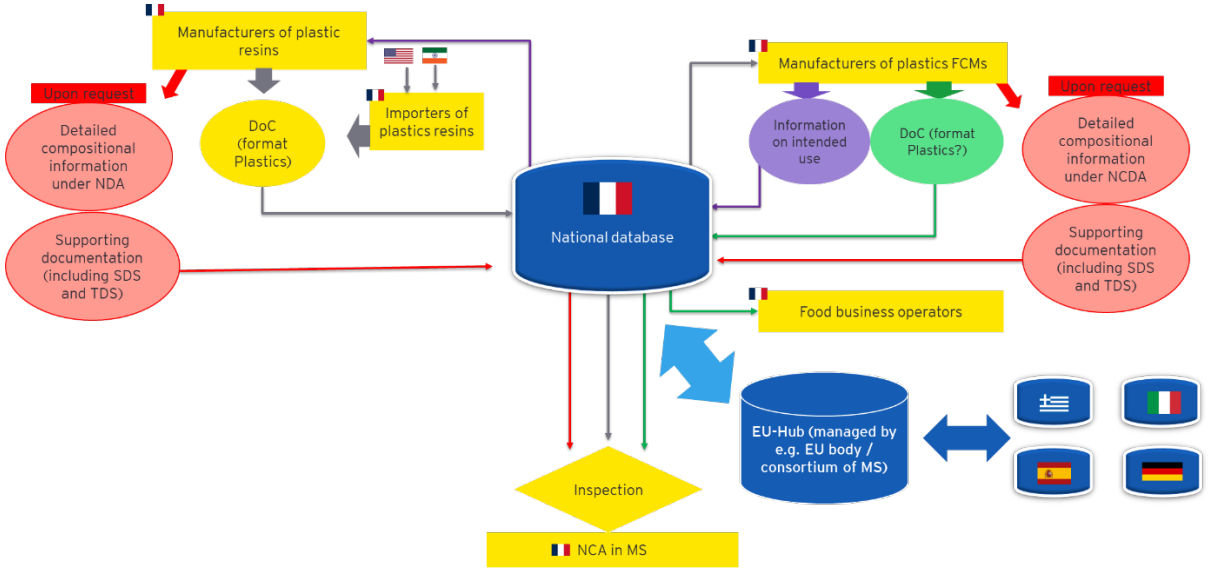
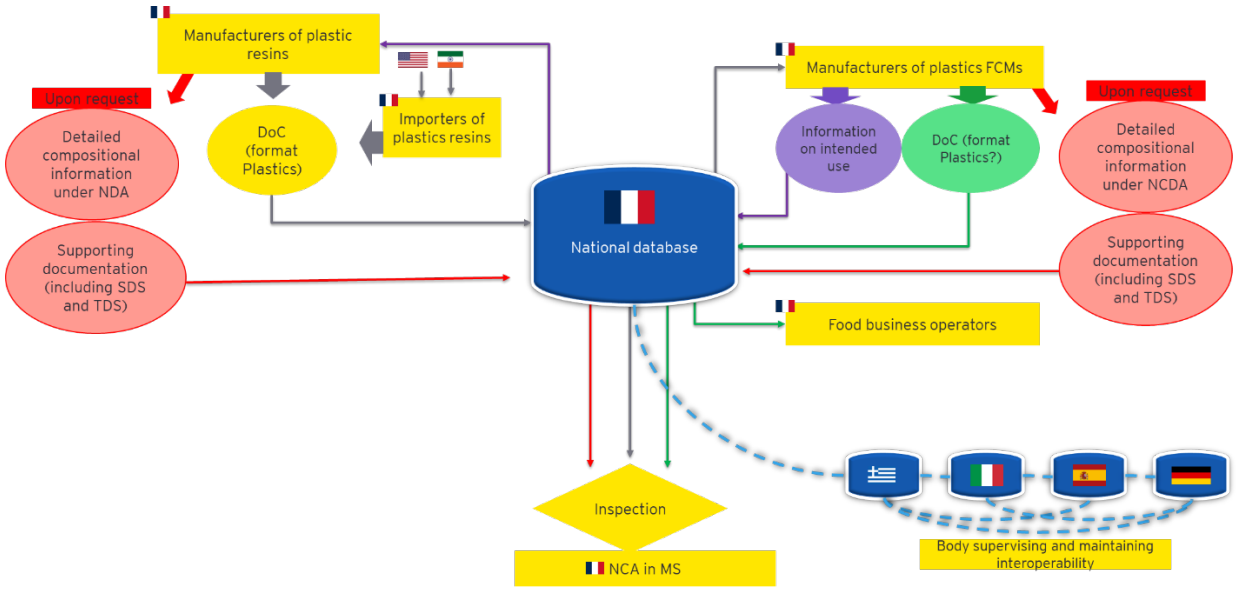


Figure 41 Application of Policy Option 2 - Decentralized IT System at Member State level to the plastics FCM supply chain (Option with interlinks between national databases for interoperability)



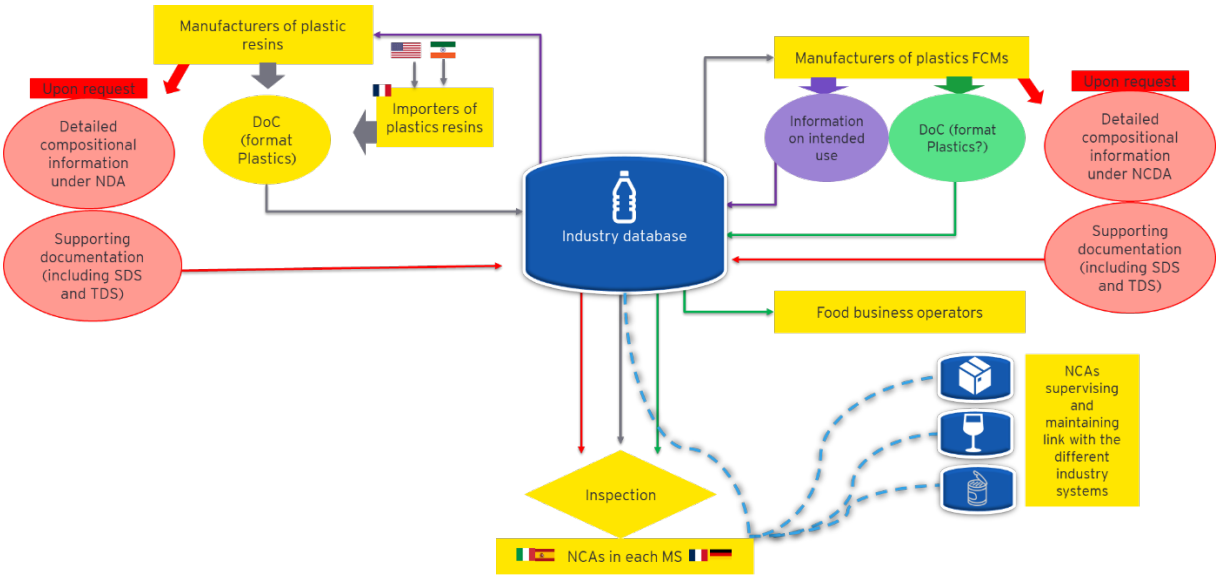
Application of Policy Option 3 for information exchange and verification of compliance in the can-making supply chain

In this policy option, a decentralized IT system is put in place with industry associations or clusters of industries responsible for management and decision-making. In this configuration, the IT system consists of decentralized industry online platforms connected to their own databases for input and withdrawal of information. Industry databases are not interoperable but rather accessible by actors in their respective supply chains and competent authorities.

The subsequent figure illustrates how a decentralized IT system, with several industry databases, would function for the case of the plastics industry.

The functionality of the information exchange in the IT system remains the same as in PO1. However, the governance of the system changes: here, various industry associations – as for instance Plastics Europe - or clusters of industries create their own databases.

Figure 42 Application of Policy Option 3 - Decentralized IT System at industry level to the plastics FCM supply chain



6.1.6. Possible impact of applying the Policy Options on this industry

The introduction of a centralized IT system for information exchange and compliance verification in the plastics FCM supply chain, with an EU body responsible for management and decision-making, would improve streamlining and unifying information exchange in the supply chain, as all actors would share information through a single, centralized platform. In addition, this system would increase transparency and accountability of all actors of the supply chain, including authorities, as they would have real-time access to data. The system would also promote harmonization and uniformity of compliance documentation and standards and improve data consistency. For verification of compliance, authorities would have a quicker access to compliance data and therefore will be able to carry out expedited verification processes. Having an EU body responsible for management of the system ensures a proactive monitoring of the overall EU supply chain and the harmonization of regulations across Member States. Business will also benefit from the standardized procedures and reduced compliance costs related to the centralization of the system.

The introduction of a decentralized IT system for information exchange and compliance verification in the plastics FCM supply chain, with Member States responsible for management and decision-making would lead to regional variations in information exchange in terms of data standards and practices, as well as in transparency and access to information. This system would create higher potential for redundancies and duplications of efforts leading to higher administrative burden. In terms of verification of compliance, verification processes could vary depending on each Member States, leading also to potential slower response times for cross-border compliance issues. The lack of a centralized coordination may lead to possible challenges related to interpretation and application of regulations. The decentralization of the IT

system may also lead to complexities that companies may have to face due to the differing systems and requirements across the EU.

The introduction of a decentralized IT system for information exchange and compliance verification in the plastics FCM supply chain, with the industry responsible for management and decision-making may lead to concerns about data privacy, potential anti-competitive behavior and conflicts of interests related to the fact that management and decision making is left to the industry. It must be secured that authorities have full access and oversight, otherwise the system may lead to potential impacts on their ability to ensure compliance.

6.2. Wood Industry

6.2.1. Introduction to the wood industry

Wood, a renewable and biodegradable resource, has gained recognition for its eco-friendly characteristics and is increasingly being used in FCM due to its safety, aesthetic appeal, and environmental sustainability. The EU has been at the forefront of sustainable forestry management practices, ensuring that wood resources are harvested responsibly. The Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification (PEFC) are two prominent certifications that guarantee responsible wood sourcing. Using wood in FCM aligns with the EU's commitment to reducing its carbon footprint and promoting circular economy principles. Furthermore, wood has proven to be a safe material for FCM when properly treated and used in compliance with EU regulations, particularly Regulation (EC) No 1935/2004. Despite its numerous advantages, wood does present challenges in FCM applications, particularly regarding cleaning and maintenance. Wood can absorb liquids and odors, making it necessary to follow strict cleaning protocols. Furthermore, the risk of allergen cross-contamination needs to be managed diligently when using wood in food preparation.

Wood is currently being used in several FCM applications. (i) Wood cutting boards and utensils are popular choices in kitchens and food preparation areas due to their natural antibacterial properties. Hardwoods like beech, oak, and maple are commonly used for these applications. (ii) Wood is increasingly used in food packaging, including crates, trays, and containers. It offers an attractive and sustainable alternative to plastic packaging materials, helping reduce plastic waste in line with EU directives. (iii) Certain wood types, such as oak and cherry, are used to enhance the flavor of food and beverages, such as wines and spirits. Wood barrels and chips are employed in the aging and flavoring processes.

6.2.2. Functioning of the wood supply chain

The supply chain of wooden FCMs is rather short. It begins with the sourcing of raw wood materials. Wood used in FCM must be derived from sustainable and legally harvested sources, adhering to EU and international regulations. Once the raw wood materials are harvested, they are transported to processing facilities. These facilities may be sawmills, wood treatment plants, or directly manufacturers of wooden FCMs. At the processing stage, the wood may undergo various treatments and transformations, including drying, planning, and shaping, to meet specific requirements for FCM production. Manufacturers specializing in wood FCM items, such as cutting boards or utensils, further process the wood using specialized equipment and techniques to ensure the safety and quality of the end product. End-users purchase and use wooden FCM products for food preparation, serving, and storage. These products can have a long service life, and when they eventually reach the end of their useful life, they are typically biodegradable and can be disposed of in an environmentally responsible manner. At the end of their life, some wooden FCM items may be repurposed or recycled into other wood products or used for energy generation.

Regular inspections, testing for chemical migration, and assessments of the finished wooden FCM products are carried out to check their quality and for structural integrity and safety of products.

6.2.3. Regulation of the wooden FCM

Wood is considered a "non-harmonized substance" under FCM legislation. This means that there are no specific EU-wide regulations or directives that solely address the use of wood as an FCM. Instead, the regulation of wood as an FCM falls under a broader framework (Regulation (EC) No 1935/2004), which establishes the general principles and requirements for FCM. However, there isn't a specific regulation exclusively dedicated to wood as an FCM. To ensure the safety of wood when used in FCM, manufacturers and businesses must comply with the general principles outlined in Regulation (EC) No 1935/2004. Additionally, the use of wood in FCM may be subject to specific national regulations and guidelines in

individual EU Member States. These regulations may vary, hence businesses using wood as an FCM may need to comply with different relevant national rules.

6.2.4. Information exchange in the wood supply chain

Actors responsible of raw material sourcing, namely forest managers, owners and/or foresters, provide information about their forest management practices, including details about harvesting, reforestation, and sustainable forestry management, to manufactures and processors of wooden FCMs.

Manufacturers and processors share information related to the treatment, processing, and transformation of wood materials. This includes details about the treatments applied to wood, such as drying and finishing processes. Furthermore, they provide information related to regulatory compliance, ensuring that wood FCM products adhere to EU regulations and guidelines. This includes documentation on compliance testing, specific migration limits, and adherence to Regulation (EC) No 1935/2004. Manufacturers usually follow a format for their DoCs that is developed nationally by their national industry associations (e.g., Siel - France). Compliance information is often documented in detailed records, including test reports and certificates of analysis. End-users, mainly large companies, receive information about the proper use, care, and maintenance of wood FCM products to ensure their safety and longevity. They may also be provided with guidance on responsible disposal or recycling options. Manufacturers do not need to receive any information from food business operators on the possible use of their products. This is due to the restricted applicability of wooden FCMs, which however does not affect the way wood is processed.

When verifying compliance, NCAs may require manufacturers and processors of wooden FCMs to provide documentation related to the treatment processes applied to the wood, such as drying methods and any coatings or finishes used, as well as information on quality control procedures, including testing records, certificates of compliance, and internal quality assurance protocols. Inspectors may require access to compliance records, including testing reports that demonstrate that wooden FCMs meet specific migration limits and other safety criteria in accordance with both FCM legislation and national requirements. Authorities may also require documentation proving that the wood used in FCM is sourced from responsibly managed forests.

6.2.5. Use case for the wooden FCM industry

Application of Policy Option 1 for information exchange and verification of compliance in the wood supply chain

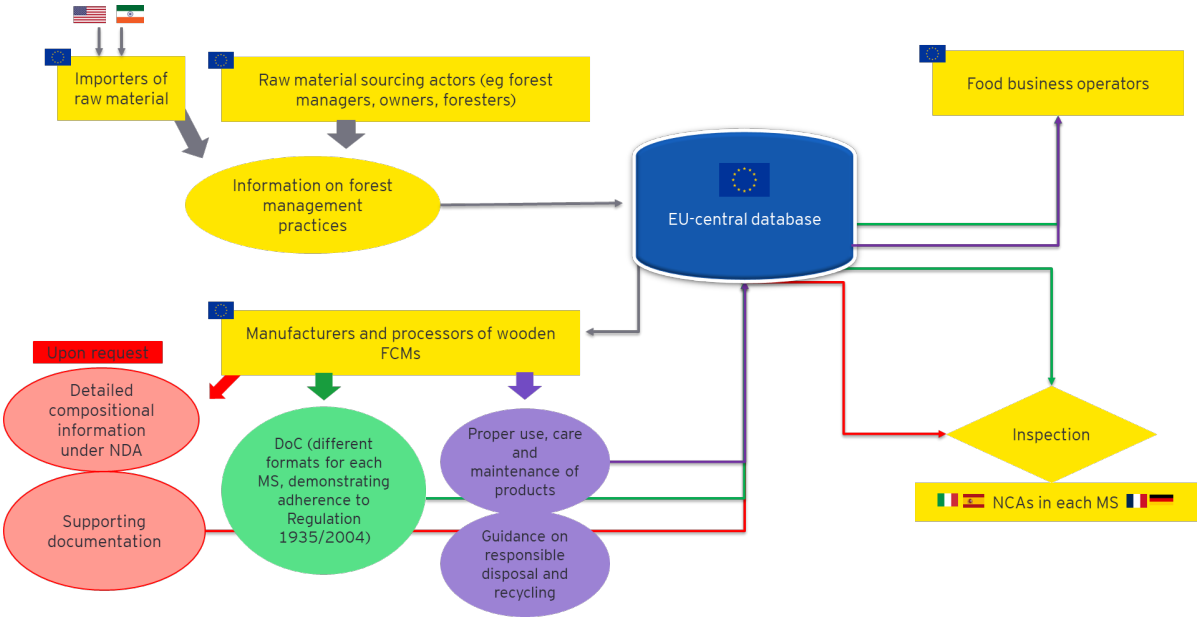
In this policy option, a centralized IT system is put in place with an EU body responsible for management and decision-making. In this configuration, the IT system consists of a centralized EU online platform connected to a central database for input and withdrawal of information.

The figure exemplifies how a centralized IT system, with a singular database primarily in use, would function for the case of the wood industry.

In this supply chain, manufactures and processors of wooden FCMs submit their compliance documents (DoCs) into the IT system. For wooden FCMs, a standardized template does not exist, rather different Member State associations have developed their own databases, therefore the necessity to devise a template is foresighted within the legislation revisioning. Until then, an option exists to input the data in formats currently used in this industry. Upon request from competent authorities, manufacturers or processors can share information under NDA or additional supporting documentation (SD). These pieces of information shall be propagated within the IT system and managed via an access authorization system (in the case of PO1, managed by the EU body responsible for decision making on the system) to make sure that only competent authorities have access to them.

Subsequent actors in the supply chain (e.g., food business operators) can access manufacturers' DoCs via the platform. The platform will facilitate entries for both raw material sourcing operators, manufactures, processors and food business operators to relay information and receive feedbacks from subsequent users on: forest management practices, proper use, care and maintenance of wooden FCMs, guidance on responsible disposal and recycling.

Figure 43 Application of Policy Option1 - Centralized IT system at EU level to the wooden FCM supply chain



Application of Policy Option 2 for information exchange and verification of compliance in the wood supply chain

In this policy option, a decentralized IT system is put in place with each Member State responsible for management and decision-making. In this configuration, the IT system consists of decentralized national online platforms connected to national databases for input and withdrawal of information. National databases are made interoperable either through an EU-Hub or through interlinks between databases.

The subsequent two figures illustrate how a decentralized IT system, with several national databases, would function for the case of the wood industry. In essence, the mode of information exchange and data gathering remains largely the same as for PO1, however the control and oversight of the system is now decentralized and relies on an interconnected web of national databases as explained for the case of the metal packaging industry.

Figure 44 Application of Policy Option 2 - Decentralized IT System at Member State level to the wooden FCM supply chain (Option with an EU Hub for interoperability of national databases)

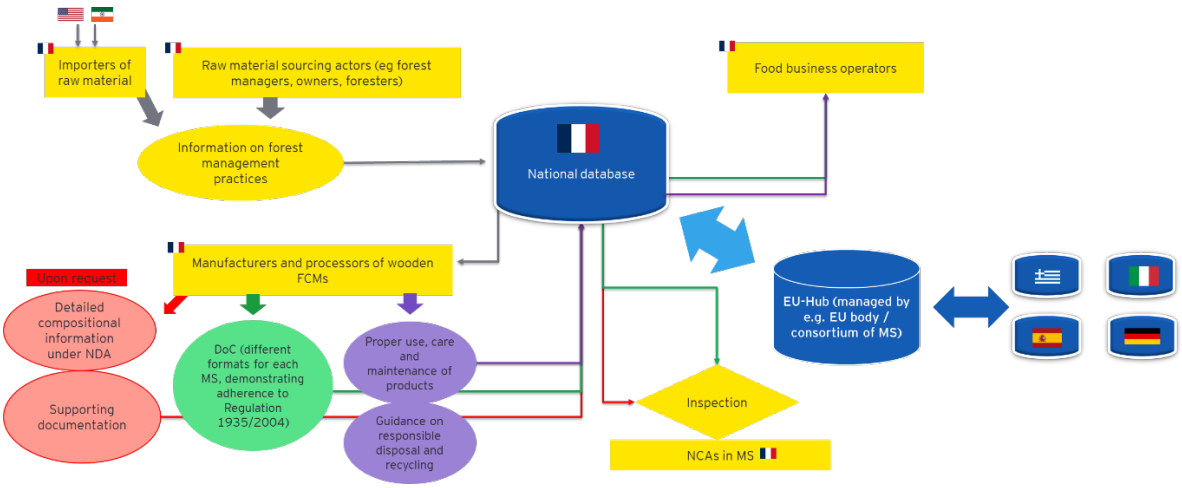
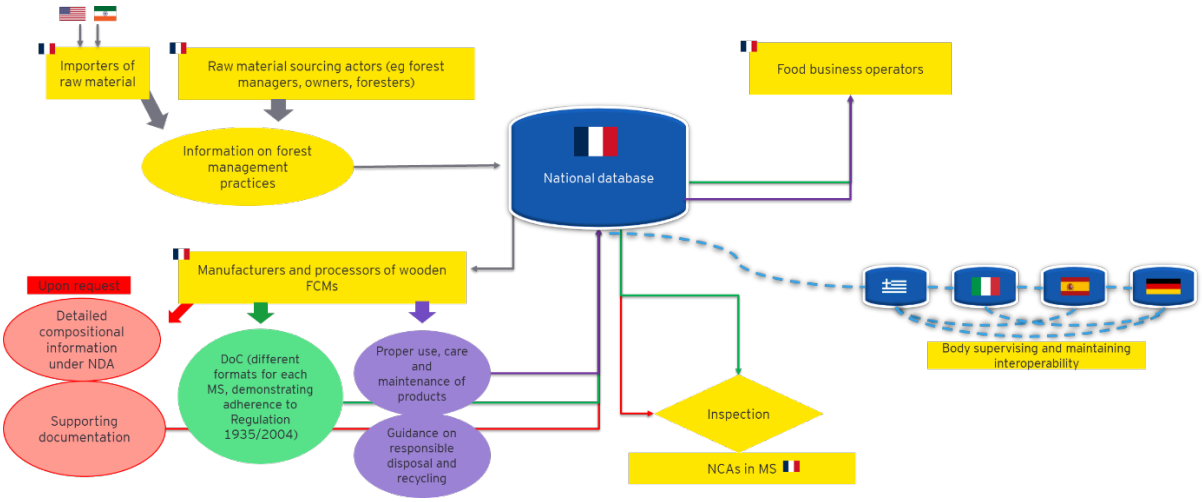


Figure 45 Application of Policy Option 2 - Decentralized IT System at Member State level to the wooden FCM supply chain (Option with interlinks between national databases for interoperability)



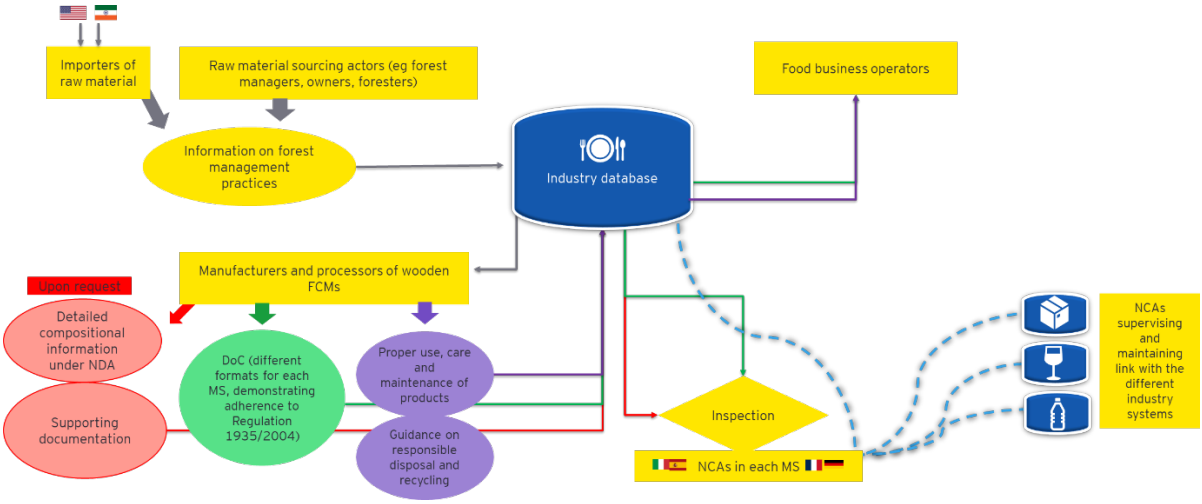
<u>Application of Policy Option 3 for information exchange and verification of compliance in the wood supply chain</u>

In this policy option, a decentralized IT system is put in place with industry associations or clusters of industries responsible for management and decision-making. In this configuration, the IT system consists of decentralized industry online platforms connected to their own databases for input and withdrawal of information. Industry databases are not interoperable but rather accessible by actors in their respective supply chains and competent authorities.

The subsequent figure illustrates how a decentralized IT system, with several industry databases, would function for the case of the wood industry.

The functionality of the information exchange in the IT system remains the same as in PO1. However, the governance of the system changes: here, various industry associations – as for instance CEI-Bois - or clusters of industries create their own databases.

Figure 46 Application of Policy Option 3 - Decentralized IT System at industry level to the wooden FCM supply chain



6.2.6. Possible impact of applying the Policy Options on this industry

The introduction of a centralized IT system for information exchange and compliance verification in the wood based FCM supply chain, with an EU body responsible for management and decision-making, would likely enhance efficiency by providing a unified platform for all involved stakeholders. Centralization would simplify data submission and retrieval, potentially streamlining the exchange of information. Moreover, it would promote consistency in data organization and standardization, mitigating the risk of discrepancies or misinterpretation among different parties. Enhanced transparency is another benefit, as a centralized system enables all actors in the supply chain to access a common database, fostering accountability and trust in the supply chain. In terms of compliance verification, centralized decision-making could lead to uniform interpretation and enforcement of regulations across Member States. This ensures a consistent approach to compliance verification. EU authorities would be better positioned for direct oversight, facilitating quicker responses to emerging issues and quicker adaptability in case of changes to the relevant legislation.

The introduction of a decentralized IT system for information exchange and compliance verification in the wood based FCM supply chain, with Member States responsible for management and decision-making, may result in a potentially more fragmented system, which would give greater margin to Member State to tailor the processes to their needs in terms of information management. In the specific case of the wood industry, this system would be beneficial to the extent that it would accommodate the several different practices of providing compliance information that have been put in place by different Member States. Interoperability and data consistency may be challenged and may necessitate coordination efforts. Concerning compliance verification, Member States could leverage their local expertise and knowledge of the wood based FCM industry to adapt verification approaches to specific circumstances. However, this approach might introduce across Member States, potentially leading to the emergence of disparities in single market. Effective coordination between Member States and EU-level bodies would be crucial to harmonize verification processes and address issues that transcend national borders.

A decentralized IT system for information exchange and compliance verification in the wood based FCM supply chain, with the industry responsible for management and decision-making, may be more efficient and technologically advanced, benefiting from private sector investments in cutting-edge solutions. Companies within the supply chain would have direct control over their data, potentially resulting in greater data ownership and management flexibility. However, concerns about transparency may arise, as industry-controlled systems could limit access to certain data or information deemed sensitive. This approach would necessitate robust oversight mechanisms to verify the accuracy and completeness of compliance data.

6.3. Metal packaging industry

6.3.1. Introduction to the metal packaging industry

Metal packaging, predominantly made of steel and aluminum, has been a staple in the food and beverage industry for decades due to its exceptional properties and ability to maintain the quality and safety of FCM. The EU metal packaging industry primarily employs two materials: steel and aluminum. Steel is commonly used for cans, while aluminum is favored for lightweight packaging like beverage cans. These metals are well-suited for FCM due to their non-reactive nature, durability, and corrosion resistance. Other materials are used in this industry to produce metal packaging FCMs, including tinplate, ECCS, lacquers, sealants, gaskets, plastics and lubricants. The manufacturing process involves forming, coating, welding, drawing, ironing, necking, flanging, beading, curling, extruding, scoring and sealing the metal sheets to create containers of various shapes and sizes. Metal packaging is well-regarded for its ability to preserve the quality and safety of FCM. It acts as a barrier against light, oxygen, and contaminants, ensuring that the packaged food remains fresh and uncontaminated throughout its shelf life. However, food and drink may be corrosive to metal. This may lead to perforation and loss of integrity and safety of the packaging material. Food may be tainted in case of corrosion of metal, change its appearance and exceed legal limits. Therefore, for most food and all beverages, metal packaging materials are coated which serves to protect the food from the metal. Currently, over 200 coatings are typically used by metal packaging manufactures. One of the standout features of metal packaging in the EU is its high recyclability. The EU has been at the forefront of promoting a circular economy, and metal packaging aligns perfectly with this vision. Recycling rates for metal packaging have consistently surpassed other materials, with aluminum achieving particularly impressive rates. Metal packaging can be tailored to specific FCM requirements. Manufacturers can adjust the thickness, coating, and design of metal containers to suit the needs of different food and beverage products.

6.3.2. Functioning of the metal packaging supply chain

The supply chain of metal packaging FCMs is a rather complex network of stakeholders involved in the production, distribution and regulation of these materials. The supply chain begins with raw material suppliers who provide steel and aluminum sheets to manufactures of metal packaging for FCM. Metal packaging manufacturers are responsible for transforming the raw materials into a wide range of products, such as cans, containers, lids and closures. Advanced manufacturing processes like deep drawing, stamping,

and shaping are used to create the desired packaging forms. During production, manufacturers may also apply various coatings and liners to enhance functionality and aesthetics. Coating suppliers play a critical role by providing the coatings and liners that are applied to metal packaging products. These coatings serve several purposes, including acting as a barrier to prevent interactions between the food and metal, ensuring food safety, and enabling product branding. The choice of coatings depends on the specific requirements of the packaging and the product it will contain. End-users of metal packaging for FCM select appropriate packaging solutions based on their product specifications, brand identity, and marketing considerations. In particular, food manufacturers fill the metal packaging with food and beverages, adhering to strict safety and quality standards to ensure consumer safety. After consumers use metal packaging, the containers can be collected through recycling programs. Recycling facilities process and prepare the metal for reuse, contributing to a circular economy.

Throughout the supply chain, quality control and compliance with EU regulations are of paramount importance. Manufacturers, distributors, and retailers must ensure that metal packaging products meet safety, quality, and regulatory standards. This includes verifying that coatings, printing, and other elements adhere to relevant food safety and packaging regulations.

6.3.3. Regulation of metal packaging FCM

The metal packaging industry is subject to specific regulations and directives, such as Regulation (EC) No 1935/2004, which sets out the general requirements for FCM, and Regulation (EC) No 2023/2006, which deals specifically with FCM made of aluminum. Some specific materials, like plastics and ceramics, have dedicated harmonized regulations that provide more detailed requirements for their use in FCM. Instead, metal is a "non-harmonized substance", meaning that there is no specific EU-wide regulation that exclusively governs all aspects of metal materials used in food contact applications. Instead, the regulation and safety of metal materials for FCM are often addressed on a case-by-case basis, taking into account specific materials, coatings, and applications. Over the last 20 years, Metal packaging Europe (MPE) representing the metal packaging industry has expressed repeatedly the need for harmonized specific legal requirements for their products and their components within the EU. Metals and alloys used in food contact materials and articles are covered by CoE Resolution CM/Res(2013)9. On behalf of CoE, the European Directorate for Quality of Medicines & Health Care (EDQM) has published a Practical Guide for the application of Resolution CM/Res(2013)9. However, this Resolution is focused on the release of particular metal ions from metallic food contact materials and articles into food rather than covering all aspects of compliance of metal packaging with framework requirements. In order to demonstrate compliance with the framework requirements for metal packaging, a cascade of applicable specific standards, national legislation, resolutions, and industry guidelines is used by the industry. For metals used in food contact applications, safety is typically assessed based on migration testing and other relevant factors.

6.3.4. Information exchange in the metal packaging supply chain

Manufacturers and suppliers are responsible for ensuring that their metal materials and coatings comply with the safety requirements and do not transfer harmful substances to food. In fact, it is the responsibility of the business operator who places food contact materials or articles on the market to demonstrate legal compliance of the materials and articles with relevant legal requirements of the food law, according to the FCM legislation. Compliance work for metal packaging is the achievement of joint efforts of a complex supply chain and the different actors in this supply chain have a shared due diligence. Metal packaging manufacturers rely on the responsible compliance work and transparent communication of their suppliers as well as on sufficient information provided by downstream users of their products.

Although there is no overall EU harmonized material specific food contact legislation for coated metal packaging which requires the use of a DoC, the principles of communication of the compliance status using a DoC have been adopted by the European metal packaging industry. The DoC should comply with the requirements laid out in EU Regulations such as Regulation (EU) 2018/213. The composition of materials such as coatings is the intellectual property of the material supplier and is generally confidential. Therefore, detailed compositional information would normally only be provided downstream under a specific Non-Disclosure Agreement (NDA) or via an independent third party. Migration data would usually be considered Supporting Documentation and does not need to be disclosed downstream but would be disclosed to competent authorities on demand. Individual metal packaging suppliers may choose to supply more information to customers on a case-to-case basis.

Metal packaging manufacturers receive from their suppliers of components, such as the metal, coatings, printing inks, can end sealants, sealing gaskets for closures and processing aids (e.g., lubricants), relevant information in order to demonstrate the consumer safety and legal compliance of their final articles. This information usually includes a DoC, as well as detailed information about the coatings and liners, material specifications, safety data sheets, any certifications and results of migrations tests and risk assessments for components of the materials which forms part of the supporting documentation provided by the material

supplier. Suppliers of components also receive compliance information from raw material suppliers in the form of DoCs.

Metal packaging manufacturers provide their customers with a specific DoC for each type of metal packaging intended to come into contact with food. There is no legal requirement with regard to the format and detailed information made available with the DoC. However, some manufacturers follow standard ISO/IEC 17025. At least the following information is usually provided with the DoC: (i) Name and address of the company which manufactures or imports the finished metal packaging, (ii) Trade name, (iii) Identity of the raw material, can sealant or coated article, (iv) Date of the declaration of compliance, (v) The confirmation that the metal packaging complies with the requirements of appropriate EU Regulations and, when appropriate, of national law under the conditions of intentional use, (vi) Adequate information relative to the substances used for which specific restrictions are in place under relevant EU or national legislation to allow the downstream user to ensure compliance with those restrictions and list of substances used for which an SML or other restrictions are established, (vi) Specifications on the use of the material or article such as - type or types of food; - time and temperature of treatment and storage of the filled metal packaging - surface/volume(mass) ratio used for compliance assessment, (vii) A statement whether or not substances, which are also dual additives are intentionally used Some information, f.i. the chemical identity of substances for which restrictions are in place may be may be subject to confidentiality agreements. In this case metal packaging manufacturer usually provide anonymized information. DoCs are usually not replaced or amended on a regular basis rather than on demand if relevant legal requirements have been amended, important properties of the respective metal packaging have been changed or new scientific knowledge has been found which is relevant to the legal compliance of the metal packaging.

For each type of marketed metal packaging for food metal packaging, manufacturers collect a set of supporting documentation which is suitable to demonstrate legal compliance of the packaging in a transparent and definite way. Supporting documentation usually contains in particular the following documents and information: (i) A DoC for each component used for the manufacture of the metal packaging, (ii) If available compliance certificates and test reports for components like metal substrates, organic coatings, can sealants and attaching parts, (iii) Risk assessment documentation for starting substances for which restrictions have to be regarded, reasoning for the selection of migration testing, (iv) Migration (overall and specific) testing reports and reports on organoleptic tests, (v) NIAS screening and evaluation with risk assessment, (vi) Results of tests for potential cross contamination (e.g. curing oven, set-off of printing ink components). Supporting documentation is not accessible for customers on a regular basis because it usually contains multiple confidential data. The set of supporting documentation will be made available to competent authorities on demand.

In many cases down-stream users ask metal packaging manufacturers to provide additional information sometimes by using individual complex questionnaires or spread sheets. In such questionnaires aspects of compliance with requirements of the food law are mixed up with other areas of legal requirements, e.g. packaging waste requirements or requirements regarding chemical safety and registration (REACH). On demand most metal packaging manufacturers are prepared to share more detailed information with their customers in particular if this is needed to demonstrate compliance of the products to retailers or competent authorities.

For an appropriate compliance work for metal packaging, it is essential that down-stream users of metal packaging provide their suppliers, manufacturers or traders with relevant information regarding the application/use of the articles. The following information is relevant for the compliance work: (i) type of food, (ii) for complex composed food the rough composition of the products including fat content, salt content and pH, (iii) processing conditions (time, temperature) and shelf life of the filled product.

Brand owners and food manufacturers seek compliance information from suppliers regarding the safety and suitability of metal packaging for their specific food and beverage products. They also need information on any changes in packaging materials or suppliers. Recycling facilities require information on the recyclability and composition of metal packaging materials to ensure proper recycling processes.

During inspections of actors in the metal packaging supply chain, national authorities typically require specific types of information to verify compliance with the FCM legislation. This includes details about the metal packaging products, the materials and components used, and safety data sheets (SDS) for coatings and inks. Authorities also seek certificates of compliance, migration testing results, production records, and traceability information to ensure that materials and manufacturing processes adhere to regulatory requirements. Hazard Analysis and Critical Control Points (HACCP) plans, quality control records, and documentation of regulatory compliance are often reviewed. This information is provided within the Supporting Documentation (SD). Metal packaging manufactures also provide explanations of technical details of metal packaging manufacture and background of chemical and physical interaction of foodstuff with different types of metal packaging. Being a non-harmonized material, Member States may have different requirements for the use of metal for FCM and would therefore require different granularity of information and/or additional proof of safety and compliance with the FCM legislation.

6.3.5. Use case for the food can-making industry (three-piece cans)

Can-making supply chain

Cans are a typical metal packaging FCM product that has been produced since the mid-19th century. Cans are composed of a cylindrical body, formed by rolling a flat piece of tinplate (ETP) that is seamed by welding. The can is then sealed at both ends, with one end being attached to the can body by the manufacturer, and the other end being sealed onto the open top of the can body after it has been filled with food. When coatings are used, they are applied on the tinplate before the can body is manufactured. Therefore, the coatings need to be flexible and resistant to withstand all the mechanical stress during the can manufacturing process. Three-piece cans may be made in almost any practical combination of height and diameter. This process is particularly suitable for making cans of mixed specifications as it is relatively simple to change the specification of can being made.

The following steps exemplify the process of production of three-piece food can bodies:

1. A steel (tinplate) strip arrives at the can manufacturing plant in large coils and is cut into large sheets. In some cases, the sheets are supplied directly pre-cut.
2. Coatings may be applied to the side of the sheets that will become the internal surface. The external surface may also be coated or printed.
3. The coated or printed sheets are dried and cured in an oven.
4. The large sheets are slit into small sheets, one for each can body.
5. Each small sheet is rolled into a cylinder or appropriate shape.
6. The cylinder edges are welded by squeezing them together and passing an electric current through that heats up the metal to create the weld.
7. The internal and optionally the external surface of the weld is sprayed with coating or powder and thermally cured.
8. The cans are flanged outwards at the top and bottom to accept the ends.
9. An end is seamed to the can body to close one end of the can.
10. The cans may be passed through a beader where the walls of the cans have circumferential beads formed in them to give added strength.
11. Every can may be tested during manufacture through a pressure tester, which automatically rejects any cans with pinholes or fractures. Cans may also pass under a vision system to check for defects.
12. The finished can bodies are then transferred to the warehouse to be automatically palletized before dispatch to the filling plants.

Exchange of information along the supply chain

To demonstrate compliance, the following actors provide specific compliance and supporting documentation to can-makers:

- Suppliers of electrolytic tinplate (ETP), electrolytic chromium or chromium oxide coated steel (ECCS also known as tin free steel (TFS)) and aluminum plate provide can-makers with a DoC. Often the format according to ISO/IEC Guide 22 is chosen for the DoC.
- Coating suppliers provide manufacturers with a written DoC for each type of coating they offer. The format of the DoC is described in the CEPE Code of Practice. It may be issued in a two-part format: part 1: General DoC, part 2: Confidential DOC. The General DoC should be available to anyone whereas the Confidential DoC contains information the supplier wants to share only with selected persons undersigned secrecy agreements.
- Can sealant suppliers provide manufacturers with a written DoC for each type of can sealant they offer. The format of the DoC usually follows the requirements for plastics as laid down in Annex IV of Regulation (EU) No 10/2011. Draft MPE (metal packaging Europe) Code of Practice for can sealants gives a detailed description of the format and content of a written DoC which is basically equivalent to Annex IV of Regulation (EU) No 10/2011.
- Sealing gasket suppliers provide metal packaging manufacturers with a written DoC for each type of sealing gasket. The format and content of the DoC follows the requirements according to Art 15 and Annex IV of Regulation (EU) No 10/2011.
- For printing inks not used for direct food contact applications, suppliers often provide DoC with the Swiss Ordinance and/or the EuPIA Guidelines. There are standards regarding the format of such declarations. For printing inks intended for direct food contact application in metal packaging, suppliers provide complete compliance documentation as they do for food contact coatings.
- Suppliers of surface lubricants and other processing aids usually provide their customers with DoCs of their products with the specified requirements and declare the suitability for application in the

manufacture of food contact articles under conditions of intended application. There are no requirements for a specific format of such declarations.

- Suppliers of lidding material and membranes provide metal packaging manufacturers with DoCs for each material they supply. Although there are no legal requirements regarding the format of DoC for coated lidding material and membranes most DoC follow the format as defined for plastic food contact materials and articles in Annex IV of Regulation (EU) No 10/2011.
- For attaching parts consisting of plastics, the supplier provides the manufacturer with a DoC according to Art 15 and Annex IV of Regulation (EU) No 10/2011. For attaching part consisting of other materials, the suppliers usually declare compliance with the framework requirements of the food contact materials and articles law. However, there is no particular format for such DoC required.

Notably, some coating manufacturers, can sealants, sealing gaskets provide copies of compliance certificates issued by independent contract laboratories. However, even in test reports and compliance certificates issued by independent contract laboratories some information, in particular the chemical identity of some starting substances, may be anonymized if it is confidential proprietary information of the raw material supplier or coating manufacturer.

As explained above for the overall metal packaging industry, can-making manufacturers depend on a smooth and transparent communication both up- and down- stream in the value chain. Therefore, they would also require information from down-stream users regarding the use of the cans they manufacture (i.e., type of food that will be contained in the can, rough composition of the product including fat content, salt content and pH in case of complex composed food, processing conditions and shelf life of the product contained in the can). Can-makers would in turn provide further information on compliance to down-stream actors by responding to questionnaires or by filling in spread sheets.

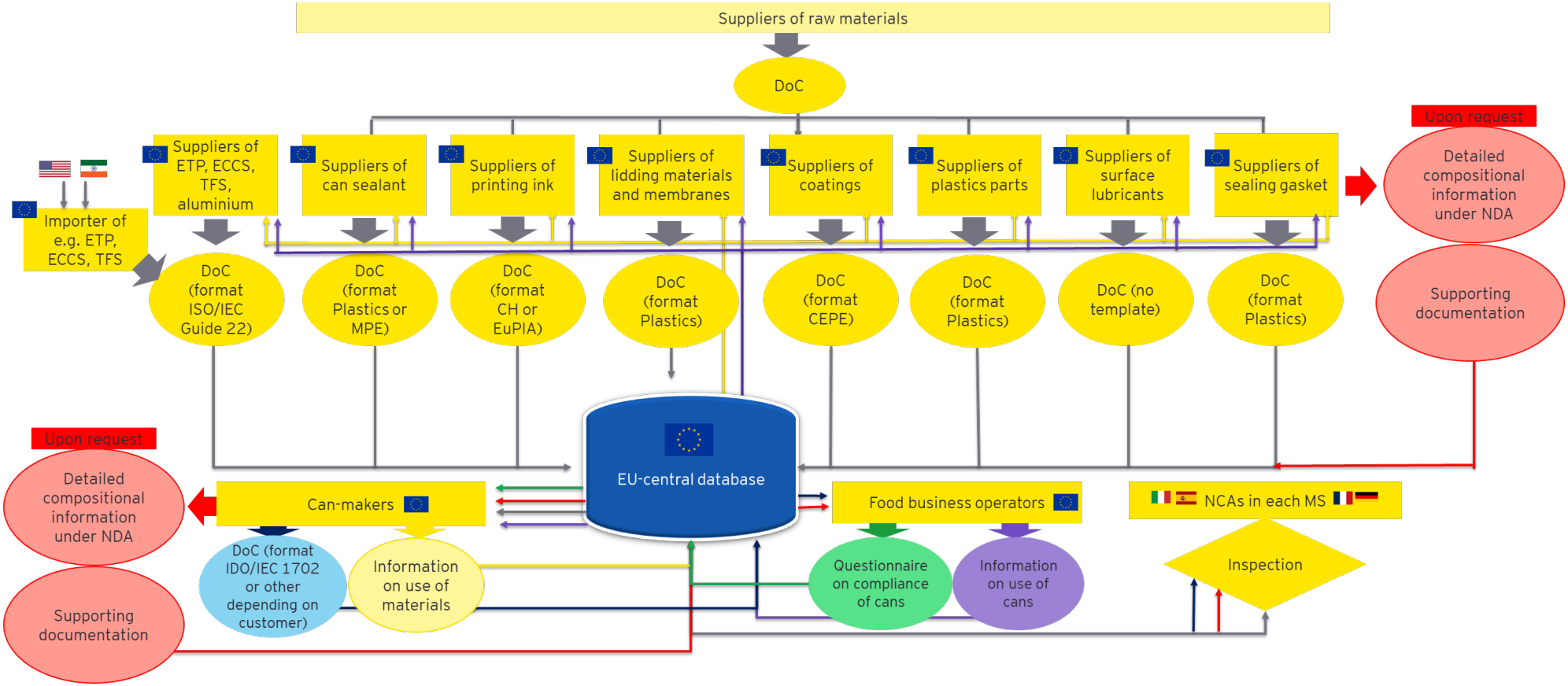
Compliance inspections

During inspections, can-makers offer a full cooperation with competent authorities in order to enable authorities to adequately enforce the legal framework requirements for materials and articles intended to come into contact with food. This cooperation regards the access to the entire supporting documentation as well as explanations of technical details of metal packaging manufacture and background of chemical and physical interaction of foodstuff with different types of metal packaging.

Application of Policy Option 1 for information exchange and verification of compliance in the can-making supply chain

In this policy option, a centralized IT system is put in place with an EU body responsible for management and decision-making. In this configuration, the IT system consists of a centralized EU online platform connected to a central database for input and withdrawal of information.

Figure 47 Application of Policy Option1 - Centralized IT system at EU level to the can-making supply chain



The figure exemplifies how a centralized IT system, with a singular database primarily in use, would function for the case of the can-making industry.

The structure commences from the top, whereby various suppliers submit their compliance documents (DoCs) into the IT system. Currently, a standardized template for the likes of plastics does not exist, therefore the necessity to devise a template is foresighted within the legislation revisioning. Until then, an option exists to input the data in diverse formats. Upon request from other stakeholders in the supply chain, suppliers can share information under NDA or additional supporting documentation (SD), but this remains at their discretion. Furthermore, these pieces of information could be propagated within the IT system and managed via an access authorization system (in the case of PO1, managed by the EU body responsible for decision making on the system). The intent is to allow these data to be visible only to relevant stakeholders. However, these pieces of information will always be available for competent authorities of the member states when required. As for actors from non-member countries, they conventionally utilize importers or have branches in a member state. Therefore, the onus lies upon them to feed the appropriate DoCs into the database.

Manufacturers, on the other hand, can access their suppliers' DoCs via the platform, while concurrently providing their DoCs to subsequent users (e.g., Food business operators). The platform will facilitate entries for them to relay information to their suppliers about the use of their materials and to receive feedback from subsequent users about the utilization of their cans. Similarly, they will be able to disseminate information under NDA and supporting documentation to other actors in the supply chain, depending on the request and the decision of the manufacturers themselves. This would be done through the same information access authorization system to ensure it reaches the appropriate actor.

From their side, the competent authorities in the member states will have the ability to access information at any time - be it before, during, or after inspections to extract necessary information for said inspections, including all necessary supporting documentation. Finally, the database could also serve as an official communication channel for interactions between authorities and supply chain actors, in case additional information is required.

Application of Policy Option 2 for information exchange and verification of compliance in the can-making supply chain

In this policy option, a decentralized IT system is put in place with each Member State responsible for management and decision-making. In this configuration, the IT system consists of decentralized national online platforms connected to national databases for input and withdrawal of information. National databases are made interoperable either through an EU-Hub or through interlinks between databases.

The subsequent two figures illustrate how a decentralized IT system, with several national databases, would function for the case of the can-making industry. The figures show that; in essence, while the mode of information exchange and data gathering remains largely the same as for PO1, the control and oversight of the system is now decentralized and relies on an interconnected web of national databases. In fact, compared to PO1, there are two distinguishing alterations:

- The governance of the system lies within the hands of the member states. Each state maintains its individual national database, where local supply chain participants input and exchange information. The competent national authorities then perform checks on these national databases.
- The national databases are interconnected either through a system of interlinks or a designated EU-Hub, allowing for interoperability between the systems. This interaction assures the free flow of information throughout the entire EU region.

Figure 48 Application of Policy Option 2 - Decentralized IT System at Member State level to the can-making supply chain (Option with an EU Hub for interoperability of national databases)

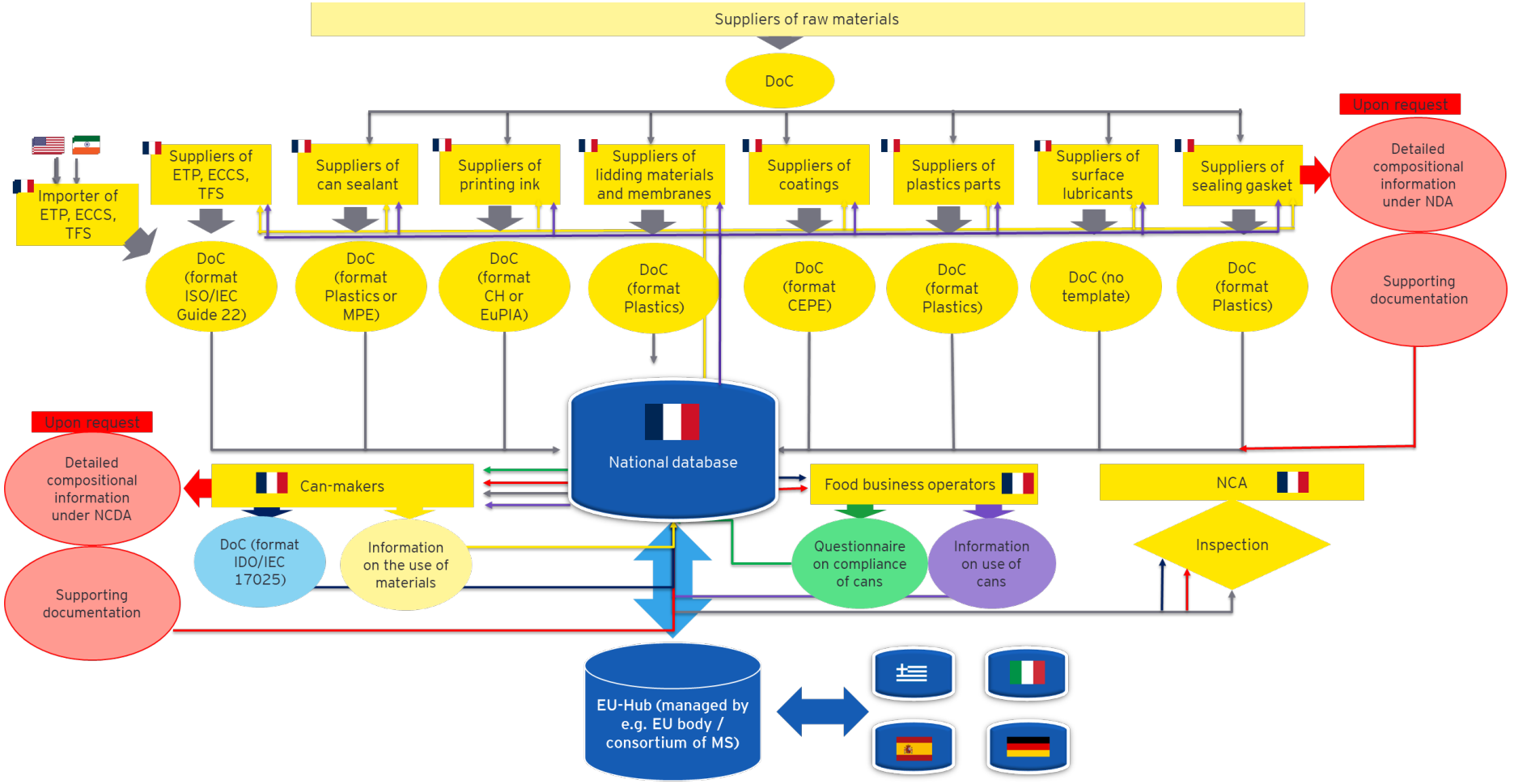
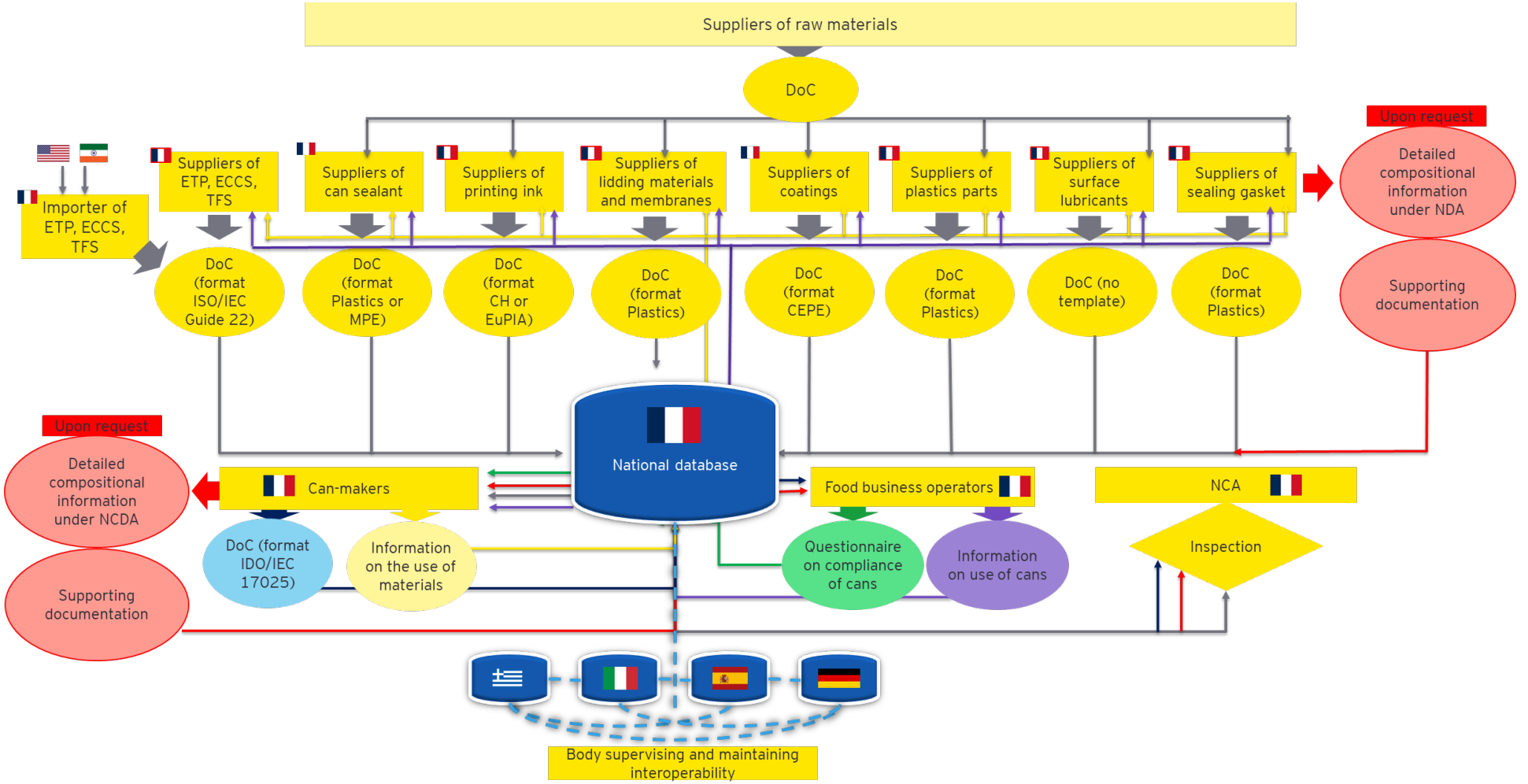


Figure 49 Application of Policy Option 2 - Decentralized IT System at Member State level to the can-making supply chain (Option with interlinks between national databases for interoperability)



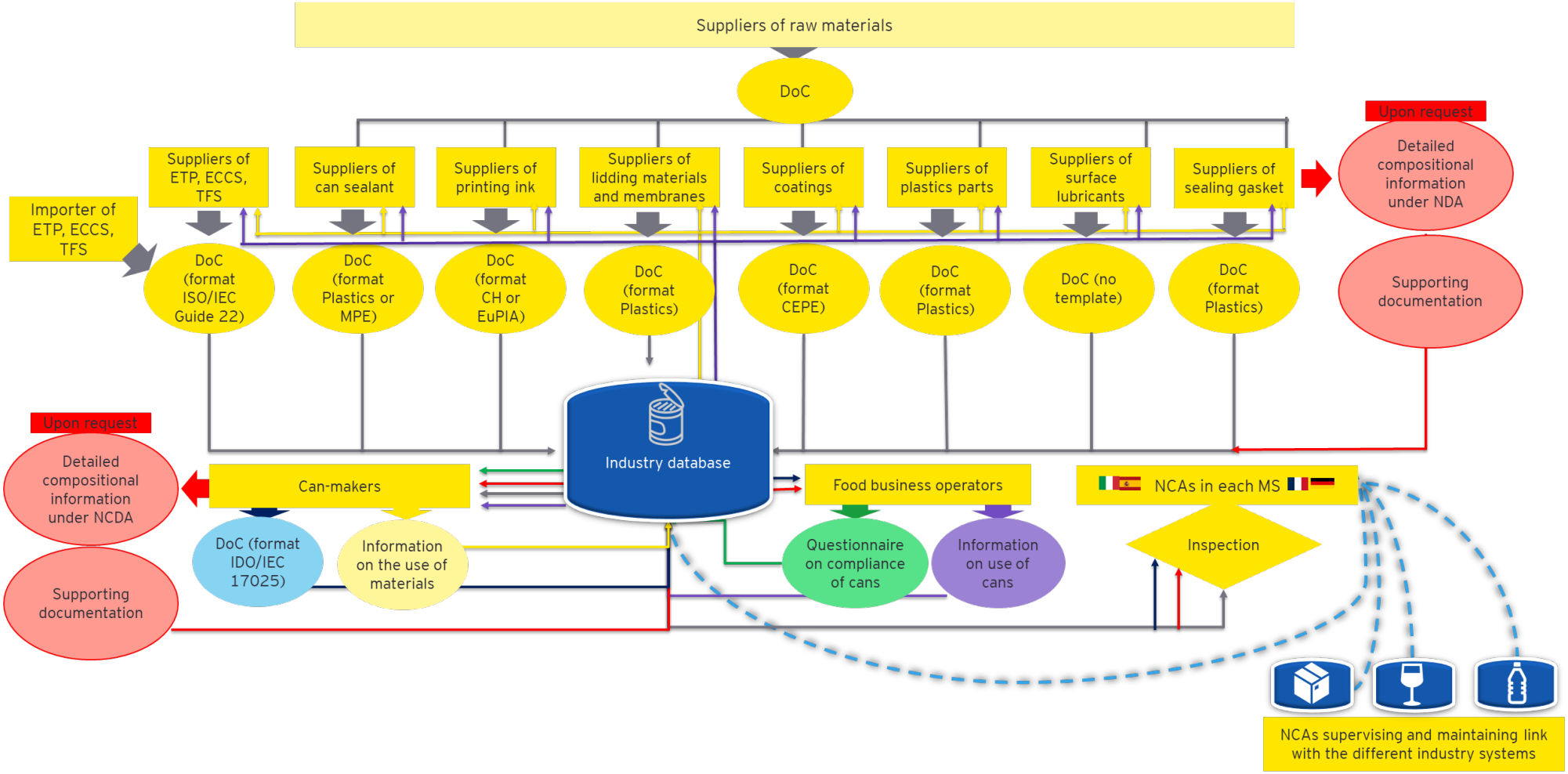
Application of Policy Option 3 for information exchange and verification of compliance in the can-making supply chain

In this policy option, a decentralized IT system is put in place with industry associations or clusters of industries responsible for management and decision-making. In this configuration, the IT system consists of decentralized industry online platforms connected to their own databases for input and withdrawal of information. Industry databases are not interoperable but rather accessible by actors in their respective supply chains and competent authorities.

The subsequent figure illustrates how a decentralized IT system, with several industry databases, would function for the case of the can-making industry.

The functionality of the information exchange in the IT system remains the same as in PO1. However, the governance of the system changes: here, various industry associations – as for instance Metal Packaging Europe - or clusters of industries create their own databases. As a result, all actors operating in diverse industry supply chains exchange information within these separate industry-specific databases. Although these databases will not have interoperability, it is important to note that competent authorities will nonetheless have access to each of these databases. This arrangement allows them to effectively carry out compliance checks of the products.

Figure 50 Application of Policy Option 3 - Decentralized IT System at industry level to the can-making supply chain



6.3.6. Possible impact of applying the Policy Options on this industry

The introduction of a centralized IT system for information exchange and compliance verification in the metal packaging FCM supply chain, with an EU body responsible for management and decision-making would promote efficiency and standardization in information exchange. All stakeholders would interact with a single platform, streamlining communication and data sharing. Centralization allows for comprehensive data integration, enabling authorities to access a centralized database of compliance information, test results, and regulatory updates. This can facilitate more informed decision-making and faster retrieval of compliance information, hence reducing the burden on business operators. Furthermore, this system could provide stronger oversight and coordination, ensuring that all Member States adhere to consistent standards and procedures, for instance for compliance verification. NCAs would have access to real-time information, aiding in the prompt verification of compliance. This could lead to quicker identification and resolution of non-compliance issues.

The introduction of a decentralized IT system for information exchange and compliance verification in the metal packaging FCM supply chain, with Member States responsible for management and decision-making allows Member States to tailor the system to their specific needs. This may promote flexibility in information exchange, which may however lead to variations in data formats and processes. Member states would have more control over data within their borders. Ensuring consistency in compliance verification could be more challenging, as challenges may arise due to varying standards, procedures, and levels of IT infrastructure across Member States.

The introduction of a decentralized IT system for information exchange and compliance verification in the metal packaging FCM supply chain, with the industry responsible for management and decision-making may lead to higher industry engagement. Industry involvement could promote active engagement and transparency in information exchange, as companies are responsible for overseeing the system for managing and sharing compliance data. The industry may be more responsive to changes in compliance requirements and could adapt IT systems accordingly. Companies would bear greater responsibility for compliance, thus possible leading to proactive verification measures. Robust regulatory oversight is however needed to ensure impartiality and adherence to regulations. There may be an issue concerning the doubling of the work for companies working in different FCM industries: in this case, they would need to enter the compliance information in several databases, which would constitute an additional burden for them.

7. Summary of Inception Impact Assessment

Between 18 December 2020 and 29 January 2021, citizens and stakeholders were invited to provide their feedback on the Inception Impact Assessment (IIA) of the Revision of European Union (EU) rules on Food Contact Materials (FCMs). There were 302 respondents, specifically:

- Companies or business organizations (45%),
- Business associations (23%),
- EU citizens (12%); and
- NGOs (8%).

Feedback was received from 18 different countries in total, including also non-EU countries, such as Switzerland (3%) and United Kingdom (2%). The majority of respondents was from:

- France (59%),
- Belgium (17%); and
- Germany (6%).
-

7.1. Feedbacks on problem definition

The main problem identified is that non-compliant FCM products still go undetected and are placed on the market, posing a risk for public health. Indeed, according to data gathered by enforcement authorities, there are still cases in which undetected substances possibly posing a risk to public health may have migrated to food. In these cases, FCMs were compliant on paper, however, upon inspections, they have been found to be far from safe in terms of the risk posed to public health. In this regard, INOVYN, a premier chemical company, claims that "experience of IT systems in

the field of REACH – e.g. IUCLID software – shows that it can be difficult to give explanations for situations which are not covered by simple "tick-box" approaches". It is indeed crucial that any system of harmonized declaration considers the specificity of each process. For example, "a raw polymer (powder) manufacturer cannot claim that their product meets global migration requirements since this requires the polymer to be melt, processed and formed into plaques in the presence of additives for migration testing: something that is carried out by downstream users. Such a company may also wish to state that compliance can be claimed under certain conditions (e.g.: maximum use level, use for non-fatty foods only etc.)"[27].

Currently, competent authorities experienced that, upon request, compliance documentation was often lacking or at least not readily available. The Danish Agriculture & Food Council confirms that "information on composition and results from migration tests of plastic materials can be withheld from the food industry" and suggests that "reliable information on all the packing material used must be available for the food industry […] [and it] must cover all relevant materials be it plastics rubber adhesives ink metal paper cardboard etc. Combinations of materials must be covered as well. (e.g. ink at paper label glued to a colored plastic foil. Aluminum lid welded to a plastic cup…)" The lack of information means that the industry is not fully capable of proving compliance of their products and that national competent authorities cannot verify whether FCMs are compliant with all legal requirements. As a consequence, non-compliant FCMs might still be entering the market.

In order to overcome these issues, "authorities will have to play an important role in approving guidance documents from industry, authorization of migrating substances, organization of work plans, and effective enforcement by checking compliance documentation".[28] In addition, another important element of the new regulation is "the method of testing migration values in addition to the migration limits. […] Test methods shall be based on real-uses in order to simulate reality rather than laboratory conditions. [29] Nonetheless, the Regulation seems to have generally improved the safety of FCM products in terms of public health. However, the problem seems to persist especially for non-harmonized substances.

Problem Driver 1: Some information is missing or not being produced at manufacturing stage

The first problem driver is that some information is missing or not being produced at manufacturing stage. For instance, the assessment of NIAS ("non-intentionally added substances") is usually disregarded by the industry. However, NIAS are impurities of the starting substances that formed as a reaction and degradation product during the manufacturing process, and they constitute the majority of migrates. The identification of NIAS is perceived as a major concern by all consulted stakeholders.[30] In particular, almost 90% of the companies consulted during the evaluation reported that they were missing adequate information on NIAS. Indeed, among others, Plastics Converters states that they "need not only a standardized format for a DoC., but rather the content of the DoCs must generally improve from the raw material suppliers´ perspective and include information on NLS and NIAS, impurities, degradation products, etc. so that converters can do an appropriate risk assessment on their final articles".[31]

In principle, all actors in the chemical industry should communicate the full information on NIAS along the supply chain. However, most of the time the responsibility of compliance of the NIAS is transferred to the producer of the final product. As stated by the European Carton Makers Association "an advanced information sharing contains also information on the used self-evaluated not listed substances, the dual use substances, the NIAS and accurate use instructions".[32] Indeed, the lack of such information makes it is difficult to perform a risk assessment at the end of the supply chain and creates obstacles for ensuring compliance of the final FCM. In fact, as aforementioned, the composition of the product might vary at each batch and the link between

[27] INOVYN (UK)
[28] Karsten Hötzer (Switzerland)
[29] Herendi Porcelánmanufaktúra Zrt. (Hungary)
[30] European Commission (2020), Study supporting the Evaluation of Food Contact Materials (FCM) legislation - (Regulation (EC) No 1935/2004)
[31] European Plastics Converters (Belgium)
[32] European Carton Makers Association (Netherlands)

used chemicals and NIAS peaks are missing, as producers of final products are not aware of the chemical composition of their products.

Problem Driver 2: Incorrect or incomplete compliance documentation

The second problem driver is the incorrect or incomplete compliance documentation. Indeed, the information contained in DoC is usually limited or underwhelming to ensure a proper assessment of compliance.[33] Most DoCs contain only basic information and are limited to mentioning compliance with the FCM Regulation and the plastics Regulation. Instead, according to Elapse and The British Plastics Federation "the content of the DoCs should also improve from the raw material supplier's perspective and include information on NLS and NIAS, impurities, degradation products, etc. so that converters can do an appropriate risk assessment on their final articles".[34] In addition, the public authorities involved in the evaluation support study reported that companies usually perceive compliance work as paperwork. Indeed, ellipse suggests that "any new system including digital solutions for exchange of information should be such as not to add unproportional administrative burden on business operators, in particular to SMEs. Outsourcing of market surveillance may be helpful in countries where the resources are insufficient. However, there must be clear rules on responsibilities. Attention should be paid to avoid conflicts of interest, and a close control and a full EU harmonization of the procedures used to carry out such surveillance should be in place".[35]

As discussed, if the exchange of safety and compliance information in the supply chain is poor, the ability to ensure compliance is compromised. Hence, it is important that a more efficient system and a greater commonality of DoCs is put in place to enable the stakeholders to access the necessary information. Nonetheless, INOVYN asks that "any scheme that is developed has sufficient flexibility to allow companies to take account of particular properties and features of their substances and materials".[36] This idea is supported also by Flexible Packaging Europe, which "would also like to draw attention to the need to have enough flexibility to combine information on different types of materials used together in one product (multi-material multi-layer product). The template also needs to work during a transition period when the regulatory status of some raw materials has already been updated and that of others not yet. Moreover, we need to be able to provide preliminary DoCs during a project launch before migration testing is completed.[37]

Problem Driver 3: Insufficient exchange of compliance information in the supply chain

The third problem driver is the insufficient exchange of compliance information in the supply chain. In fact, the evaluation found that the obtainment of adequate supporting information through the whole supply chain is challenging. In this regard, INOVYN maintains that "as a company which is, by definition, at the very start or close to the start of supply chains, the information being placed into the chain is accurate and informative and provides the means to enable further assessments to be made after compounding and conversion". [38] Nonetheless, it is essential that "every operator in the food value chain takes its responsibility of evaluating the risks for their specific step in the chain, and inform the next operator in the value chain on topics or limitations that may have influence on the safety of FCMs at later production stages".[39] Yet this seems to be a particularly difficult exercise. Even though it is clear that transparency is key, as "the food business operator, suppliers, and manufacturers of FCMs must exchange adequate information to ensure the safe use of the final article",[40] supporting information is more difficult to obtain. Even if "transparency about the flow of information in the supply chain can never be 100%", Vouwkarton Platform Nederland suggests that "by tackling the unassessed substances in a responsible pragmatic way - taking in account hazard and exposure - further progress may be

[33] European Commission (2022), Commission Staff Working Document: Evaluation of the legislation on Food Contact Materials - Regulation (EC) No 1935/2004
[34] Elipso (France) ; The British Plastics Federation (UK)
[35] Elipso (France)
[36] INOVYN (UK)
[37] Flexible Packaging Europe (Germany)
[38] INOVYN (UK)
[39] Stora Enso (Finland) AND Confederation of European Paper Industries (Belgium)
[40] UNESDA Soft Drinks Europe (Belgium)

made" as ultimately "communication and a clear determination of responsibilities in the supply chain is essential for making progress regarding the safety of FCMs". [41]

In this context, both public authorities and business in the evaluation pointed out that ensuring the completeness and quality of DoCs from imported FCMs is challenging, as they both lack access to the previous segments of the supply chain. Exchange of safety and compliance information in the supply chain is poor and the ability to ensure compliance is compromised: "it is important that a more efficient system is put in place to enable these stakeholders to access the necessary information. More formal templates for the Declaration of Compliance can help achieving such objective. But in addition, the cost of compliance and the ability of SMEs to take on this new responsibility should not be underestimated".[42]In addition, as International Carbon Black Association (ICBA) suggests, another issue might be that "without positive lists it will be difficult for raw material producers to ensure suitability of products for use in FCMs and to efficiently communicate along the supply chains. If, in the future, the focus changes to specific migration limits that apply to the final article, raw material producers will no longer be able to assess their starting substances, and hence communication on compliance status of starting materials along the supply chain will be impacted negatively".[43]

Other obstacles to consider are confidentiality issues and lack of knowledge, particularly among SMEs. This is a central matter for certain industries and actors in the supply chain. For instance, Stora Enso "would welcome EU guidance to incentivize and promote the transparency needed for this to function properly".[44] Indeed, according to them, "exchange of information along the supply chain is a prerequisite for food safety".[45] Nonetheless, "at the same time, these guidelines need to bear in mind that the intellectual property (IPs) of the companies involved needs to be protected as it can be compromised, if sensitive information is demanded to be disclosed".[46]

In addition, in supply chains that include non-EU countries, it becomes difficult to identify imported FCMs (e.g.: in case of recalls or withdrawal from the market). For instance, as it was difficult to gather the needed information from different Member States or third countries, SFIF strongly supports the intention to improve quality and accessibility of supply chain information for compliance and enforcement, especially the fact that "the imported materials will need to fulfil EU rules too".[47]

Ultimately, a more efficient system is needed to enable all stakeholders to access to appropriate information. For example, MOL Group supports "the introduction of clear and consistent rules on data requirements and information transfer throughout the supply chain. A digital information system would be welcome to make the process more efficient and to eliminate paperwork"[48]

Problem Driver 4: Limited capacity of Member States to enforce the legislation

The evaluation pointed out that capacity of Member States to enforce the legislation is limited. It has been identified that the system lacks a comprehensive checklist for compliance check, guidance documentation including for the evaluation of DoCs and that controls are poorly documented. Indeed, ArcelorMittal Europe states that they "see merit in a framework that would be better harmonized across Member States, and in the standardization of supply chain communication, for example regarding Declarations of Compliance. Clearing up certain definitions would also be beneficial to clarify the scope and applicability of rules and requirements for food contact materials".[49] Furthermore, it has been highlighted that the "transposition of the EU directive resulting from the resolution into national legislation stills allows some divergence between EU Member States on issues where there was still not yet complete agreement."[50] APPLiA

[41] Vouwkarton Platform Nederland
[42] The British Plastics Federation (UK)
[43] International Carbon Black Association (ICBA) (United States)
[44] Stora Enso (Finland) AND Confederation of European Paper Industries (Belgium)
[45] Stora Enso (Finland) AND Confederation of European Paper Industries (Belgium)
[46] Stora Enso (Finland) AND Confederation of European Paper Industries (Belgium)
[47] Swedish Forest Industries Federation (Sweden)
[48] MOL Group (Hungary)
[49] ArcelorMittal Europe (Luxembourg)
[50] EU Citizen (Belgium)

suggests that the priority should be "for the Commission to closely develop EU harmonized rules for current non-harmonized FCMs, in particular, "metals and alloys" and "silicones and rubber", among others. Indeed, in general, it is worth noticing that there is a lack of harmonized EU-wide rules for certain materials, which leads to uncertainty among all partners in the supply chain as to what the food contact Declaration of Compliance (DoC), and other supporting documents, must include. Non-EU harmonized FCMs constitute a real challenge for manufacturers of home appliances in both scenarios, i.e.: when the materials are regulated at the national level, and when they are not". [51] They also point out that "if FCMs are regulated at the national level, issues are generated because of different and contradictory existing national rules (e.g. different RA/RM, different testing methods, and different (substance) specific migration limits (SMLs)). On the other hand, if FCMs are not regulated at the national level, RA/RM are defined and undertaken by business operators (in compliance with Article 3 of the Framework Regulation), which base themselves on the upstream information received via the supply chain. we would recommend for this approach to render a homogeneous and transversal manner to RA/RM chemicals in the EU, through synergy between ECHA, EFSA, and relevant Member States authorities. setting clear EU-rules and obligations on information exchange to each actor of a supply chain, while not forgetting to take into account current sector-specific complexities, would improve the flow-of-information and establish a smooth transfer of relevant data up and down." [52]

In other cases, the presence of DoCs and SDs is not granted, as they are not required beyond specific materials. In the latter case, Member States and industry are free to define their own approach: "This has added to the fragmentation of the internal market for foodstuffs and reduce transparency to the detriment of both industry and consumers".[53] Therefore, "harmonized rules for FCMs are crucial in providing a defined level of safety in the EU. The variety of national legislations regulating material in contact with food creates disparities among Member States and thus, an uneven level playing field. Further, companies facing these different national requirements incur administrative and technical burdens and higher costs of compliance. Specific regulations targeting plastic FCMs have in fact enabled harmonization at the EU level on the risk assessment, by creating uniform rules on compliance, which facilitates such process for the industry and thereby ensures a high level of safety".[54]

Ultimately, accurate communication and a clear determination of responsibilities in the supply chain is essential for making progress regarding the safety of FCMs.

7.2. Feedback on policy options

Based on the responses to the Inception Impact Assessment, the following can be summarized.

- "A digital/online platform solution should be constructed so that it does not violate the companies right to protect their proprietary information. Such database should be developed to leverage the opportunities of digital solutions but at the same time not to add additional burden on the systems which is populated vastly by SMEs. Likely impacts on simplification and/or administrative burden" (Elipso (France))
- "Digitalization can be the right way to improve the quality and accessibility of information, although it must be done in a very systematic and gradual way. It should be noted that a lot of small businesses, particularly in the traditional food craft sector, have not yet adapted to the digital age and may require an alternative route to obtaining compliance documentation. SMEunited demands to ensure that all enterprises, regardless of their size, can use and benefit from digital information technologies and enquires to further assess the feasibility for SMEs of using digital means. Moreover, regarding the new data requirements and information transfer, we ask for a proper impact assessment as well as for simplified procedures and streamlined administrative tools". (SMEunited (Belgium))
- "With regard to the comment that "the legislation would therefore benefit from integration of a more modern, simplified and digitalized system commensurate with progressing technological and IT standards, to improve accountability, information

[51] APPLiA - Home Appliance Europe (Belgium)
[52] APPLiA - Home Appliance Europe (Belgium)
[53] Danish Agriculture & Food Council (Denmark)
[54] Plastics Recyclers Europe (Belgium)

flow and compliance work" we point to discussions about the development of a repository of information but also to urge that any new IT system still requires the oversight of suitably qualified and experienced individuals to ensure that it is both fit for purpose and not overly bureaucratic."(INOVYN (UK))

- "For safety and compliance assessment of FCM, the compliance (supporting) documentation is the key. Insufficient compliance work is the main obstacle against an adequate communication within the supply chain. Hence, digitalization of a template for the declaration of compliance is not of first priority." (Karsten Hötzer (Switzerland))
- "We would also like to draw attention to the need to have enough flexibility to combine information on different types of materials used together in one product. The template also needs to work during a transition period when the regulatory status of some raw materials has already been updated and that of others has not yet. Moreover, we need to be able to provide preliminary DoCs during a project launch before migration testing is complete. Any new system including digital solutions for exchange of information should be such as not to add unproportional administrative burden on business operators, in particular to SMEs."(The British Plastics Federation (UK))
- "We agree with the concept of a simplified and digitalized IT system at EU level and recognize that it will greatly assist Competent Authorities in carrying out their duties. It is for this reason that APEAL participates in several working groups which brings together actors in the rigid metal packaging sector and coating industries to bring about the development of systems that can demonstrate that relevant risk assessments have been undertaken. Should the Commission feel that it needs to propose the use of IT systems at an EU level, any proposed tools should be evaluated on the basis of effectiveness, efficiency, and user friendliness, so that external expertise is not required in the act of submission of information to the authorities". (APEAL - the Association of European Producers of steel for packaging (Belgium))
- "Once such risk assessments are carried out and completed, the communication of the outcomes should be facilitated. We recommend the development of a data repository for both virgin and recycled plastics that will provide more transparency and simplify access to information for enforcement authorities. Such a repository could support chain of custody information flows, and the application of new technologies that do not impede the recyclability of the material - such as digital watermarking – should be considered to improve communication along the value chain". (Polyolefin Circular Economy Platform (Belgium))
- "MOL Group supports the introduction of clear and consistent rules on data requirements and information transfer throughout the supply chain. A digital information system would be welcome to make the process more efficient and to eliminate paperwork". (MOL Group (Hungary))
- "SFIF agrees that improvement is needed concerning the content in declaration of compliance documents. Digitalization together with an education focused on practical applications are tools that contribute to improvements. It is important that the development of DoC is made in collaboration with actors along the entire value chain". (Swedish Forest Industries Federation (Sweden))
- "We also believe that a more modern, simplified and digitalized system commensurate with progressing technological and IT standards, could improve accountability, information flow and compliance work for both the industry and the competent authorities." (Stora Enso (Finland))
- "We also believe that a more modern, simplified and digitalized system corresponding with progressing technological and IT standards, could improve accountability, information flow and compliance work for both the industry and the competent authorities". (Confederation of European Paper Industries (Belgium))
- "vzbv therefore welcomes the European Commission's proposal of a fully digitalized system for Declarations of Compliance. Such a system must ensure that the economic actors provide safety documentation throughout the supply chain as well as evidence related to safety assessments. This system can contribute to facilitating the work of competent authorities. Only FCMs that are accompanied by comprehensive safety documentation should be allowed to be placed on the market. Ultimately, the system

needs to be at the heart of an EU-wide approval scheme for all FCMs. The safety documentation can only be meaningful and effective if there are clear and comprehensive rules in place. Positive and negative lists can create a framework to carry out safety assessments and document compliance." (Federation of German Consumer Organization (Verbraucherzentrale Bundesverband; vzbv) (Germany))

- "We support the proposal to include DoC for all FCM and enhance the transparency of information within the value chain following the rules of confidentiality (where needed). However, there is no one size fits all solution as we see in practice every day. For example, the risk of a substance can be digitalized in an information system and be easily accessible. The situation with final article is completely different, as the safety of the article is evaluated for every specific application and food stuff. The means of an information system should be carefully designed to fit the needs and abilities of all actors across the value chain. Final article producers are often SMEs which would need to work with the system and often lack the resources and means to effectively use the benefits of such a system. A well-defined information sharing is essential for all stakeholders, especially the SMEs." (FEFCO (Belgium))
- "Presently the principal problem is inadequate compliance work onto which the information in the supply chain, i.e. the declaration of compliance, could be based. It is widely known that many declarations of compliance are not adequately supported, but since usually no alternative products with better safety assessment are available and "anyway nothing will happen" or "competitors do the same", poor declarations are accepted. A digitalized template for the compliance declaration does not help. Authorities/regulations should focus on the compliance work. They should remind the producers about the potentially relevant subjects to be addressed in the compliance work, e.g. in the form of a checklist for the compliance documentation (as proposed in a draft Technical Guide by the Council of Europe), not in a template for the declaration. When a supplier declares compliance, it should be specified what had to be taken into account to enable this declaration, and the customer should feel sure that the compliance work was complete. The declaration of compliance is derived from the compliance documentation. The easiest way of drafting the declaration is going point by point of the documentation, for each point deciding what needs to be conveyed to the customer. Hence the format of the declaration should be left open or adjusted to a check list of the documentation. A template imposed by legislations does not seem conducive – it tackles the problem of poor information in the supply chain from the wrong end. […] Digitalization of the compliance declaration is not the most relevant step forward. A template risks neglecting certain points and might miss the opportunity for a better solution, such as a link to the compliance documentation, as the declaration is derived from the documentation. Usually the compliance work is more of a problem than its communication." (Koni GROB)
- "As for exchange of information in the supply chain in a digital manner, it is often difficult for retailers to get all the information needed from suppliers. Introducing clear and consistent rules and responsibilities on information requirements and transfer throughout the supply chain could address this issue. Such rules need to be built on exiting IT systems and not try to replace them or duplicate them. Caution is nevertheless needed regarding new and expanded data requirements and information sharing needs which requires a proper impact assessment. Digital solutions need to be analyzed on their scope, application and benefits for the end user and care should be taken not to duplicate reporting requirements." (EuroCommerce (Belgium))
- "Any new system including digital solutions for exchange of information should be such as not to add unproportional administrative burden on business operators, in particular to SMEs." (European Plastics Converters (Belgium))
- "The EWF also welcomes the creation of an integrated, more modern, simplified and digitalized system commensurate with progressing technological and IT standards, to improve accountability, information flow and compliance work. We agree that once this system is available, it will greatly help both the Competent Authorities and our member companies to carry out their duties." (European Wax Federation aisbl (Belgium))
- "ERP particularly welcomes the European Commission's proposals to integrate a modern, simplified and digitalized system for material and compliance data

management as this would substantially improve the information flow and, thereby, enhance the confidence on FCMs including recycled materials, leading to an increased demand for the latter to leverage further the excellent information generated within the REACH legislation over the past years to further enhance public safety". (European Recycling Platform (Germany))

- "The legislation would therefore benefit from integration of a more modern, simplified and digitalized system commensurate with progressing technological and IT standards, to improve accountability, information flow and compliance work." (CPME (Belgium))
- "Regarding the idea to collect all information fully digitalized in one system, Henkel wants to point out that clear rules must be established to ensure a reliable platform for the data transfer and also for the access to this detailed information. The technological progress of each individual company needs to be protected in the best way possible in order to invite all industry sectors to develop innovative solutions for safer and more sustainable products and to contribute to the recyclability of all materials, so that the targets of the EU Green Deal can be reached." (Henkel AG (Germany))
- "For the issue "Exchange of safety and compliance information in the supply chain", this is especially important when FCM uses recycled plastic material and if they are coming from outside of the EU or developing area in the EU. Recyclates coming from such region may have competitive price but they are generally weak in exchanging safety information. Since majority of suppliers can be SMEs, some harmonized, simplified and digitalized system is necessary. Introducing of such technology/standard may also give competitiveness to recyclates produced according to the defined rules. However, when any digitalized system will be established, one should also consider that recycled content methodology and chain of custody approach has been discussed in the industry that integration of system can be considered e.g. RAL-Gütegemeinschaft für PET-Getränkeflaschen (https://www.wertstoff-pet.de/en/about-us/). In terms of compliance information existing activities e.g. digital watermarking technology and its data management should be also reviewed." (ALPLA Werke Alwin Lehner GmbH & Co KG (Austria)).

8. List of sources

Category	Document
Legislation	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.
	Commission Regulation (EC) No 2023/2006 of 2006 on good manufacturing practice for materials and articles intended to come into contact with food
	Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain.
	Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food
	Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food
	Council Directive 76/893/EEC of 23 November 1976 on the approximation of laws of the Member States relating to materials and articles intended to come into contact with foodstuffs
	Consolidated text: Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food
	Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs

Category	Document
	Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs
	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
EU Policy Documents and Studies	Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain
	Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
	European Commission (2022). Study on compliance documentation on food contact materials (FCMs) in the supply chain
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Category	Document
	European Commission, Health and Consumers Directorate-General (2010). Final report of a specific audit carried out in Italy from 04 to 12 October 2010 in order to assess the official control systems in place for food hygiene, traceability, labelling, food contact materials and food additives in the context of a general audit
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	Eurostat (2021). Turnover in Plastics industry by country (NACE C222) – euros
	Eurostat (2021). Turnover in Paper and Paperboard industry by country (NACE C17) – euros
	Eurostat (2021). Production in Paper and Paperboard by country – tonnes manufactured
	Eurostat (2020). Import-export flow of Plastics and Rubber products by country (NACE C22) – euros
	Eurostat (2020). Import-export flow of Paper and Paperboard products by country (NACE C17) – euros
Guidance Documents	Risk assessment and guidance documents prepared by Plastics Europe, available at https://plasticseurope.org/sustainability/plastics-health/safety-of-plastics/food-contact/
	EuPIA Guideline on Printing Inks applied to Food Contact Materials, April 2020 available at https://www.eupia.org/wp-content/uploads/2022/09/2020-12-22_EuPIA_Guideline_on_Printing_Inks_applied_to_Food_Contact_Materials.pdf
	Policy positions on metal packaging, Metal Packaging Europe, available at https://metalpackagingeurope.org/information-hub#smooth-scroll-top

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