# Study supporting the Impact Assessment on the revision of the EU legislation on food contact materials

Working Group

**5 July 2023**

Building a better working world

# Agenda

# Who we are

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# 1 Objectives and scope

# The Study has one overall objective focusing on three general objectives

**Overall Objective**

Support HaDEA and DG SANTE in the pillar relating to information exchange, compliance and enforcement in relation to the amendment of legislation relating to food contact materials.

Elaborate different options (specifically 3) in relation to an IT infrastructure that is required for information exchange.

Assess the impacts of such options.

Examine the manner in which compliance and controls of FCMs may be carried out.

# Scope of the Study

## Content

**Cover all food contact materials including:**

- **Food packaging**
- **Food processing and transportation equipment**
- **Appliances**
- **Table and kitchenware and their components**

## Timeline

**Cover first years after the adoption of the future regulation**

## Territory

**Cover all EU27 Member States and highlight potential differences in the situation of specific countries/regions**

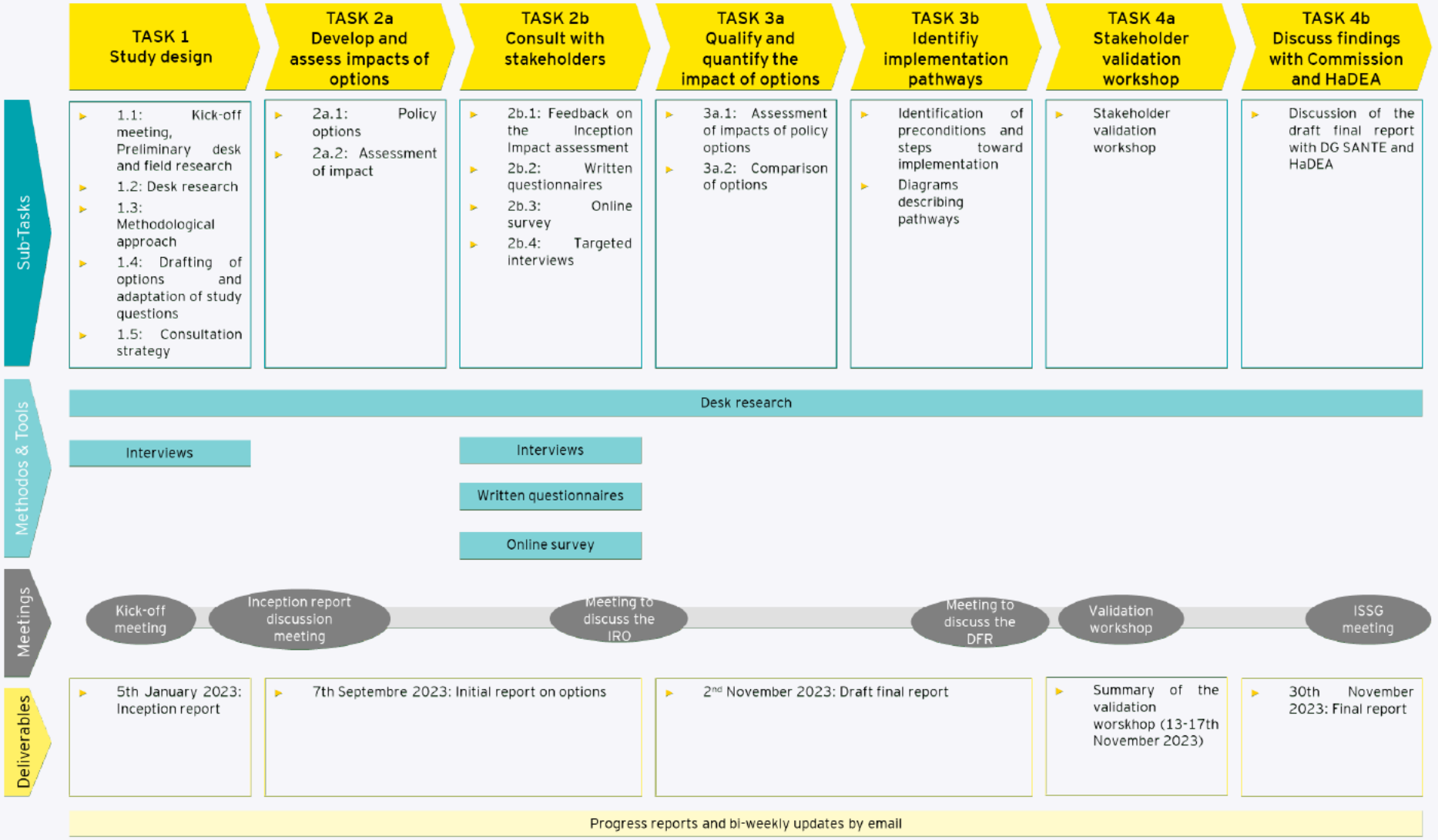
## Stakeholders

- **EU institutions and bodies**
- **Member States' Competent Authorities**
- **National reference laboratories**
- **FCM compliance testing services**
- **FCM professional organisations**
- **Individual business operators**
- **NGOs**
- **Consumers' organisations**
- **Specified scientific institutes, experts and private laboratories**
- **International stakeholders and organisations**

# 2

# Methodological Approach & Work undertaken

# Our Proposed Approach



# Work undertaken for the Inception Report (validated on 1 June 2023)

| | |
|---|---|
| **Step 1.1 Kick-off meeting** | A kick-off meeting was held on 7 December 2022 between DG SANTE, HaDEA and EY. |
| **Step 1.1 Preliminary Field Research** | Exploratory interviews were undertaken with 7 stakeholders from the following organisations: **NCAs, FCM experts, business associations, industry, European Commission** |
| **Step 1.2 Desk Research** | Analyse the legal basis of FCMs and examine the evolution of its legislation and policy.<br><br>Identify and select the relevant documentary sources in the following tasks |
| **Step 1.3 Methodological Approach** | Refinement of the Study Questions and preparation of a detailed analytical framework |
| **Step 1.4 Drafting of options** | Prepare the groundwork for the design and future implementation and assessment of the Policy Options. |
| **Step 1.5 Consultation Strategy** | Refinement of the Consultation Strategy and selection of stakeholders |

# Focus on: preliminary Field Research

**Objective**

Gain an in-depth understanding of the context of the Study and the existing needs in order to fine-tune the methodological approach.

Exploratory interviews were undertaken with 7 stakeholders from the following organisations after the kick-off meeting:

- **National competent authorities:** Danish Veterinary and Food Administration (Ministry of Food, Agriculture and Fisheries); German Federal Ministry of Food and Agriculture
- **FCM Experts:** Koni Grob (Kantonales Labor Zürich)
- **Business associations:** EuPIA (European Printing Ink Association); Metal Packaging Europe
- **Industry:** Foodchain ID
- **European Commission:** DG SANTE Unit 1

# Focus on: Desk Research

**Objective**

Inform the problem definition and analytical approach to the study questions. Select relevent documentary sources to be analysed in the following tasks of the study.

| | | | |
|---|---|---|---|
| Analysis of responses to the Inception Impact Assessment | Review of audits on FCM legislation and official controls 2008-2018 | Preliminary research on case studies (e.g. Medical devices & IMDS automotive industry | Analysis of industry guidance documents |

In addition, a review of the below documentation was conducted:

- **Legislation** (e.g., Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food)
- **EU Policy Documents and Studies** (e.g., JRC Baseline study, FCM legislation evaluation and supporting study)
- **European datasets** (e.g., Eurostat)
- **Guidance documents** (e.g., EuPIA Guideline on Printing Inks applied to Food Contact Materials, April 2020).

# 3

## Focus on: Consultation activities

# Our data collection strategy focuses on 5 key tools

01

## Interviews

Investigate in detail the consequences of the implementation of future policy options.

At least 40 interviews with a representative sample of the different stakeholder constituencies, at both the EU and national level

02

## Survey

Target industry representatives to collect information and points of view on the proposed options from businesses whose positions may not be reflected by EU-level professional organizations and that are too numerous to be consulted through interviews

03

## Written questionnaires

Two questionnaires targeted to: (i) Member State competent authorities and (ii) national reference laboratories.

Collect points of view from stakeholders that the Study will not be able to exhaustively consult through interviews.

04

## Open Public Consultation

Analyse the feedback received to the Open Public Consultation (OPC) launched by the European Commission. We will retrieve relevant information and concerns raised according to the Study questions and other topics. A data base would be developed and allow the consolidation of relevant feedback

05

## Workshop

A one-day workshop to present emerging findings from the analysis and provide a further opportunity for wide participation of stakeholders in the process/ obtain validation from experts in the field as to the robustness of the analysis.

# Stakeholder categories engaged in consultations

| Written Questionnaire | Online survey | Targeted interviews |
| --- | --- | --- |
| • National reference laboratories<br>• National Authorities & National Competent Authorities | • EU-level professional associations (businesses and SMEs) | • 10 Member States<br>• Industry representatives<br>• EU bodies<br>• FCM experts |

# Written Questionnaires to Member States

**Objective**

Gain insights regarding future policy options concerning the exchange of information, compliance and enfoncement, particularly the set up of an IT infrastructure for information exchange in the FCM supply chain.

**To whom?** Member State Competent Authorities, National Reference Laboratories

**How?** Deployment of written by email. The questionnaire will be in English but may be responded to in the national language if such issues arise.

**Status** **All Member States have already received our written questionnaire**. Only one Member State has provided a response as of today (Lithuania). Member States will have until **14 July 2023** to respond.

# Online Survey to the Industry

**Objective**

Gain industry insights throughout the supply chain on information exchange, complaince and enforcement.

**To whom?** Industry stakeholders via representative EU business associations

**How?** The Online questionnaire is dispatched with a link via the EY Qualtrics Survey tool. An open link shall enable industry members of the EU organisations to disseminate the survey to the industry at large.

**Status** **We have received 170 responses from members of EU industry associations**. Additional members will have until **10 July 2023** to respond.

# Targeted interviews

**Objective**

Supplement written data collection to fill in data gaps, enhancing our qualitative data collection.

**To whom?**

Representative sample of **10 Member States** (National Competent Authority), Industry Representative, EU Institutions & EU-level associations, selected FCM experts.

**How?**

Interviews to be undertaken either in Brussels (for the EU-level associations) or on Microsoft Teams. Requests for interviews will be circulated via email with the accreditation letter provided by the Commission. An interview topic guide will be sent to the interviewee prior to the interview.

**Status**

**22 EU-level industry associations** have been contacted for interviews, as well as **10 Member State authorities** (Austria, Denmark, France, Germany, Greece, Hungary, Italy, Poland, Slovakia, Sweden) and **8 EU/international Institutions and agencies**.

# Open Public Consultation (OPC)

**Objective**

Gain insights on stakeholders' positions regarding the problems and possible solutions by analysing the responses to the OPC (5 October 2022 – 11 January 2023)

**Analysis of OPC responses:**

- 609 responses were received from 31 countries. Largest number of respondents in the EU from: France, Germany, Hungary, Belgium.
- The largest number of respondents were EU citizens as well as business organisations and associations.
- Among relevant respondents, large majority of SMEs and Micro organisations (215).
- Carried out qualitative analysis of 115 position papers targeted to gathering evidence to support (i) problem definition, (ii) policy options – in particular the set up of an IT system, (iii) other solutions to improve information exchange and enforcement, (iv) current practices across industries on information exchange

# Stakeholder Workshop

**Objective**

Review, discuss and/or confirm the findings of the study and provide further inputs.

**Whom?**

All stakeholders and experts that have been consulted over the course of the study, including representatives in charge of other IT systems taken into account in this Study. We anticipate an attendance of between 40 and 50 stakeholders.

**When?**

The Study Team proposes that the Workshop be held in the **first half of November**, following the submission of the final report.

**How?**

An in person workshop to be held in Brussels. If the Commission premises are not available, the Study Team shall work to secure a space in the EY offices in Diegem. Stakeholders will receive an official invitation letter.

# 4

# Focus on: Case studies

# Case studies

**Objective**

Identify concrete impacts of changing the current system in order to be able to assess both qualitatively and quantitatively the impacts associated with the three Policy Options

| | | |
|---|---|---|
| **To whom?** | Three Case Studies which would focus on **concrete examples (different industries facing different difficulties) of how information is currently exchanged** through the supply chain | Two Case Studies focusing on the **introduction of IT systems that could be used to identify best practices** and practical examples of what impacts have occurred |
| **How?** | Undertaken following the completion of the other data collection tools highlighted above | These comparative Case Studies can begin earlier in the data collection process than the three Case Studies presented besides |

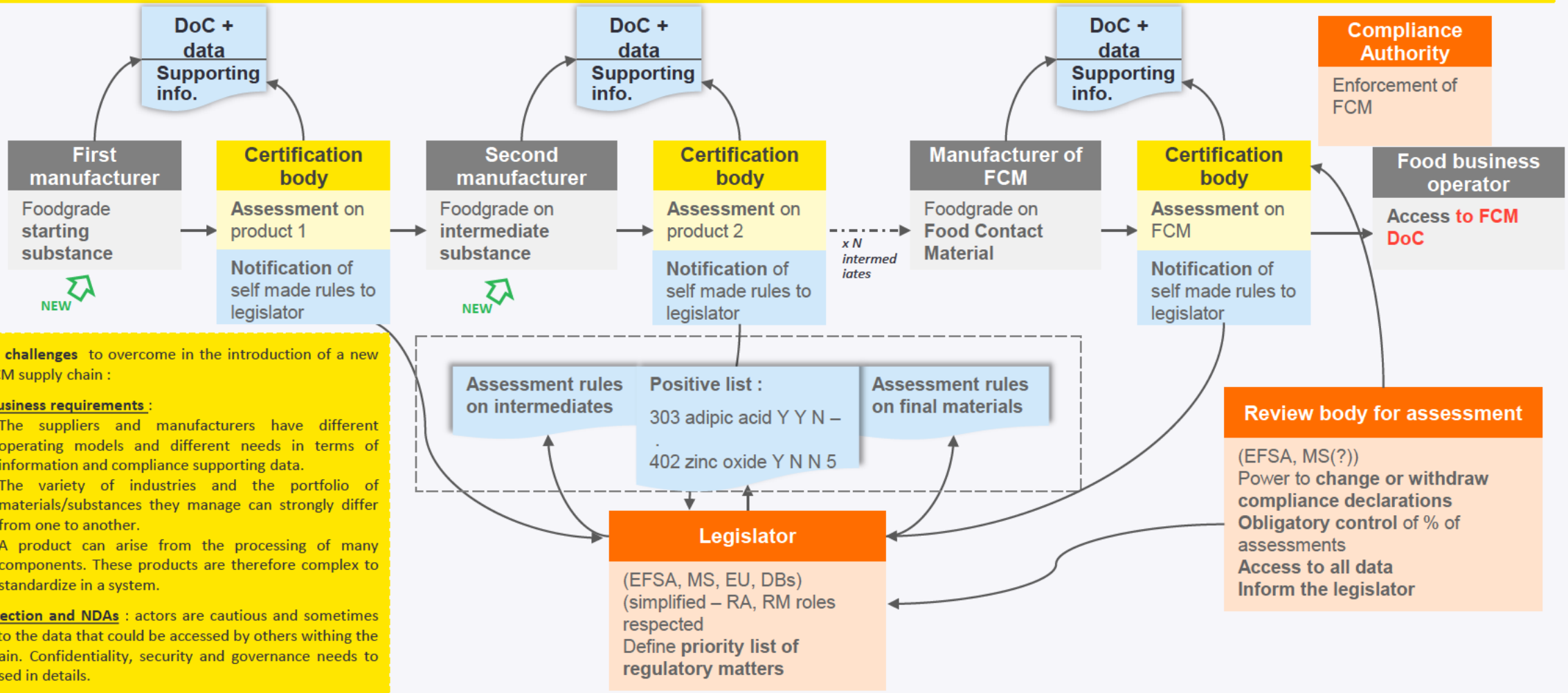
# Similar systems in the EU

| | **IMDS** International Material Data System | **EMVS** European Medicines Verification System | **REACH-IT** | **TRACES NT** - Trade Control and Expert System New Technology |
|---|---|---|---|---|
| **Industry** | Automotive | Pharmaceuticals | Chemicals | Agricultural and food industries |
| **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. |
| **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.<br>Implemented in 2019, it aims to improve the identification and authentication of medicinal products by implementing a standardized verification process across EU member states. | 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. |
| **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. |
| **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 |
| **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. | 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. |
| **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.<br>National authorities designated by EU Member State are responsible for enforcement. |

# 5

## Focus on: Policy Options & IT System

# Supply chain process for FCMs and its challenges

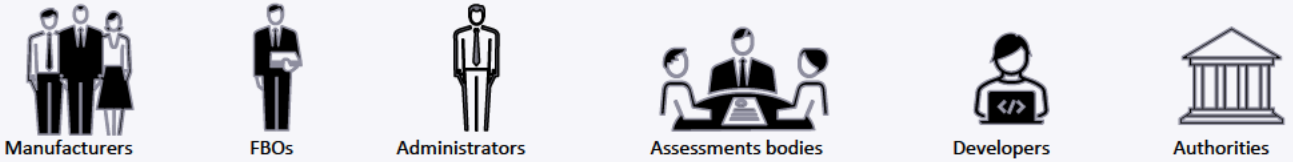



There are many **challenges** to overcome in the introduction of a new system in the FCM supply chain :

- **Diverse business requirements** :
  - The suppliers and manufacturers have different operating models and different needs in terms of information and compliance supporting data.
  - The variety of industries and the portfolio of materials/substances they manage can strongly differ from one to another.
  - A product can arise from the processing of many components. These products are therefore complex to standardize in a system.
- **Data protection and NDAs** : actors are cautious and sometimes reluctant to the data that could be accessed by others withing the supply chain. Confidentiality, security and governance needs to be addressed in details.
- **Integration with legacy systems** : the industrials already have their own systems and databases, a smooth integration and interoperability are key.
- **Non-EU actors** with limited knowledge and/or compliance with EU legislation.

# Main elements for the FCM system for information exchange and assessment

**Stakeholders**




## BUSINESS PROCESSES

Maping out current macro-processes and requirements in terms of information exchange and evaluation for future macro-processes to be included in an IT system.

## APPLICATIONS & TECHNOLOGIES

Applications and technologies that structure the system's components and their interactions. It has to ensure scalability, maintainability, flexibility and reliability of the software system.

**Data entry and retrieval**

**QR Codes**

**Blockchain (EBSI)**

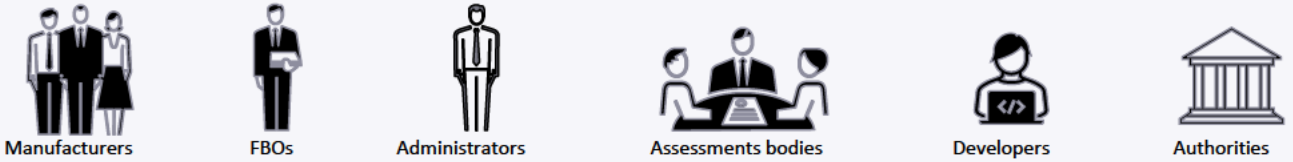
## DATA & INTEROPERABILITY

Data architecture and functioning :

- Data Management
- Data sources
- Data protection
- Data governance
- Data storage
- ...

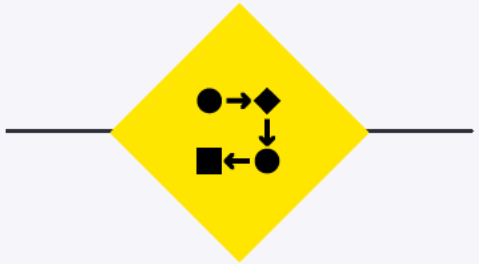
# To what extent can the stakeholder consultations help the study ?

**Stakeholders**




**Study questions**

## BUSINESS PROCESSES



- Understanding compliance information exchange
- Collecting types of data required to verify compliance
- Understanding risk assessment within the production chain
- Determining responsibilities regarding data entry and maintenance
- Projecting on the functioning for non-EU suppliers

## APPLICATIONS & TECHNOLOGIES

- Working on minimizing the burden of data access for actors responsible for FCM articles
- Data access for enforcement authorities
- Studying the technologies that can be used
- Optimizing the system for SMEs

## DATA & INTEROPERABILITY

- Data strategy (storage, security, etc.)
- Existing data integration into the new FCM system

# Policy-options and decision making

1

**Centralized system with an EU body responsible for management and decision-making**

2

**Decentralized system with Member States principally responsible for local management and decision-making**

3

**Decentralized system with national industries responsible for management and decision-making**

*It should be noted that :*

- *Even if the decision-making and the management is specified in the 3 options, the enforcement can be carried out by other bodies depending on the authorizations/habilitations of the system. For example, a system centralized by the EU can allow access to each national authority to carry out the enforcement of regulations.*
- *For each of the systems presented earlier (REACH, IMDS, EMVS, TRACES NT) the necessity of collaborative operations between EU, Member States and industries remains the first requirement to the functioning.*

# Step 1.4 Preliminary impacts

An initial set of impacts has been set, against which the Policy Options shall be assessed.

1. **Centralized system with an EU body responsible for management and decision-making**
2. **Decentralized system with Member States principally responsible for local management and decision-making**
3. **Decentralized system with national industries responsible for management and decision-making**

| Assessment criteria | Preliminary impact | Indicator Examples |
|---|---|---|
| **Policy objectives - Effectiveness** | SO1. Allow for easy access to information on the composition and safety of FCMs | Number of materials/substances for which information on its composition and safety is available |
| | SO2. Allow for easy verification of compliance information and enforcement | Number and proportion of official checks in which compliance documentation is made available to competent authorities |
| **Economic Impact** | Impact on administrative/compliance costs | Administrative/compliance costs per stakeholder type |
| | Impact on businesses | Number of FTEs needed to ensure compliance of current regulation<br>Number of FTEs needed to ensure compliance with future legislation |
| **Social Impact** | Impact on food safety | Number of non-compliant FCM products entering the market<br>Number of controls of FCM |
| | Impact on consumers | Type of information available to consumers |

# Any questions for us?

- Any reactions on the **policy options** presented?
- Would you have any **preference** regarding the different options presented (centalised, decentalised system)?
- How do you feel about the **benefits and challenges of implementing a new IT system for FCM**?

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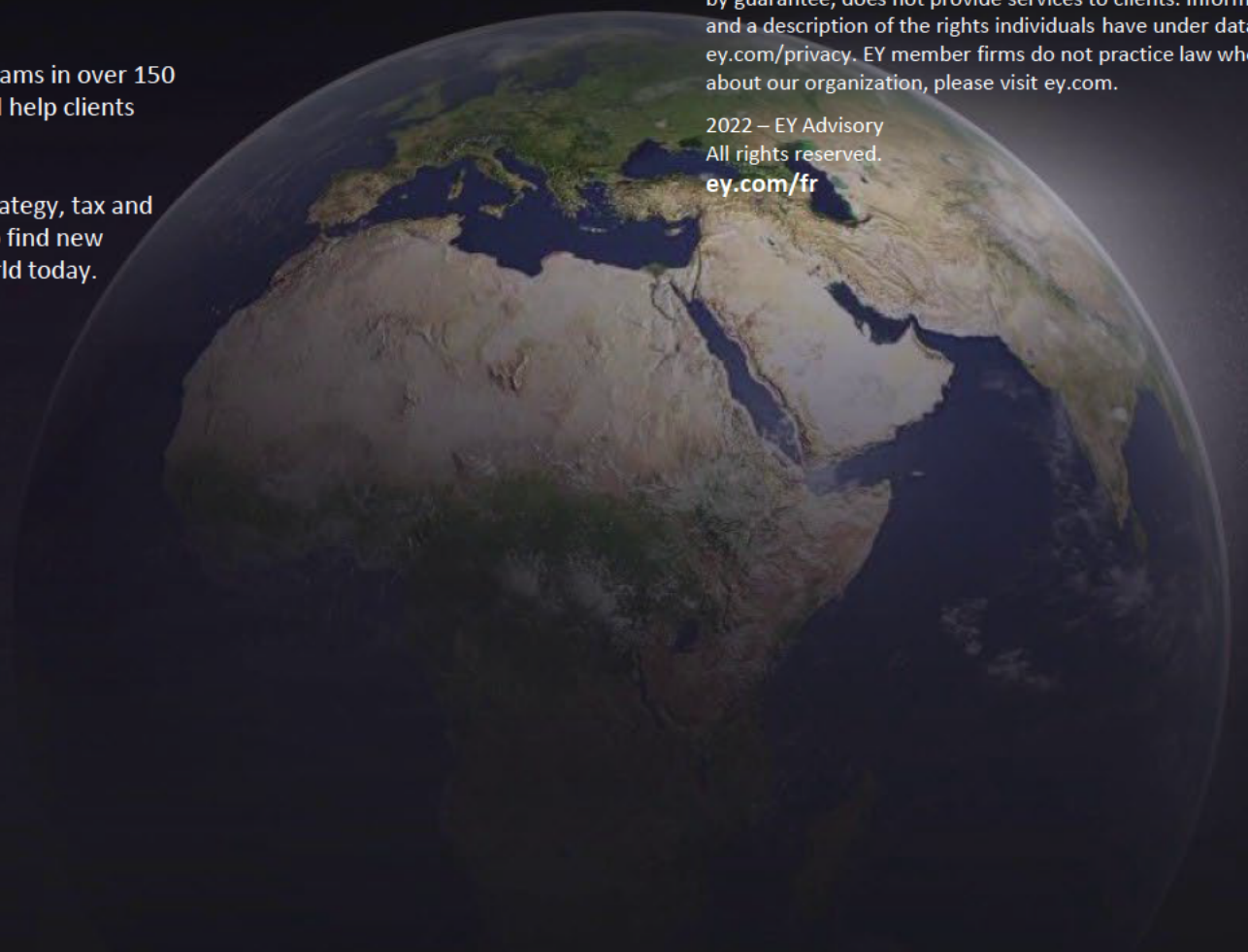



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