

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

Validation workshop

15 March, 2024

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The better the question. The better the answer.  
The better the world works.





# Workshop agenda



# The Study Team

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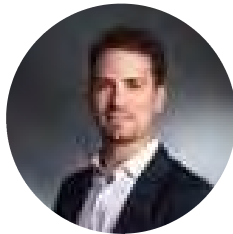
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# Objectives and functioning of the workshop

## Objective



**This validation workshop aims to present the results of the study, discuss and validate the findings and obtain insights from stakeholders to complete the final report.**

## Functioning



### Presentation sessions

**Don't hesitate to write down questions in the chat. We will do our best to address them later in the workshop.**



### Times for discussion

**We expect active participation during discussion sessions. We will propose questions to guide the discussion.**

### Your contact for technical support

If you need technical support, you can contact Marco Laoreti  
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# Workshop agenda

March 15<sup>th</sup>, 2024

## Study supporting the IA on the revision of the FCM legislation







### Morning

#### Session 1 – Presentation of the study and the policy options

9:30 – 10:10		Introduction by the European Commission DG SANTE
10:10 – 10:30		Q&A on Commission presentation
10:30 – 11:00		Presentation on the context, objectives and methodology of the study
11:00 – 11:15		Coffee break
11:15 – 11:30		Presentation of the policy options to support the establishment of IT systems
11:30 – 12:30		Discussion and feedbacks from the participants

### Afternoon

#### Session 2 – Impacts of policy options and their implementation

14:15 – 14:45		Presentation of the results of the assessment of impacts
14:45 – 15:15		Discussion and feedbacks from the participants
15:15 – 15:30		Coffee break
15:30 – 15:45		Presentation of implementation pathways and preliminary conclusions of the study
15:45 – 16:00		Discussion and feedbacks from the participants
16:00 – 16:30		Conclusions by the European Commission DG SANTE



Session 1

# Presentation of the context of the study and the objectives

# Ensuring food safety through the FCM legislation

## Food Contact Materials (FCM) refers to any material that comes in direct contact with food

- ▶ This includes packaging, utensils, storage containers, and machinery.
- ▶ FCMs can influence the safety of the food, due to transfer of their constituents which may impact human health.
- ▶ Ensuring the safety of these materials is crucial, especially since they are involved in all stages of food production, from processing to final consumption.

## The European Union first started regulations on FCMs in 1976 to secure high level of human health protection and functioning of the internal market

- ▶ Council Directive 76/893/EEC, later revised into Regulation (EC) No 1935/2004, forms the main FCM legislation and regulates the production and supply of FCMs.
- ▶ The regulation mandates that these materials should not transfer their constituents to food in amounts that could pose a risk to human health, alter food composition, or cause deterioration in the food's organoleptic properties.

## First formal evaluation of EU FCM legislation was completed in 2022

- ▶ Challenges identified include limited availability of DoCs, difficulties tracing FCMs from raw materials to finished products, and limited information on Good Manufacturing Practices (GMP).
- ▶ Inconsistencies and gaps in the declarations of compliance were identified. These can lead to lapses in information transmission and potential non-compliance.
- ▶ The Evaluation concluded a need for modernizing and digitizing FCM systems for improved accountability, transparency, and ease of compliance.

## In light of the evaluation and as part of the Farm to Fork Strategy, the Commission has planned to revise EU FCM rules

- ▶ The ultimate aim is to establish a robust regulatory system for FCMs that fosters food safety, public health protection, market effectiveness, and sustainability.
- ▶ Pillars D and E of the revision focus primarily on information exchange, compliance, and enforcement in the FCM supply chain.

# The scope of the study is related to Pillars D and E of the revision of the FCM legislation

Safety and sustainability of FCM			
Main pillars of the revision	<b>Pillar A</b> Redress focus onto final material	<b>Pillar B</b> Prioritisation of substances	<b>Pillar C</b> Supporting more sustainable alternatives
	<ul style="list-style-type: none"> <li>Better define the level of safety required, addressing the full characteristics of all final FCM articles and migrating substances, including NIAS</li> <li>Cluster into broader material types (synthetic, natural, inorganic, recycled, composite, active)</li> </ul>	<ul style="list-style-type: none"> <li>Define rules for the risk assessment of all substances that migrate from FCMs</li> <li>Tiered approach:                             <ul style="list-style-type: none"> <li>Tier 1: generic risk based</li> <li>Tier 2: risk assessment by public authorities</li> <li>Tier 3: Self-assessment by business operators of more benign substances</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Ensure fewer hazardous chemicals</li> <li>Prioritise more sustainable use of FCMs</li> <li>Coherence and support to other EU rules on sustainability, including packaging and food</li> </ul>
Information exchange, compliance and enforcement of FCMs			
Support pillars	<b>Pillar D</b> Improving quality and accessibility of supply chain information	<b>Pillar E</b> System for verifying compliance and undertaking of official controls	<b>Pillar F</b> Analytical methods
	<ul style="list-style-type: none"> <li>Clear and consistent rules on data requirements and information transfer throughout the supply chain, including a DoC for all FCMs</li> <li>Digitisation to help businesses, including SMEs to ensure compliance and for MS to enforce</li> </ul>	<ul style="list-style-type: none"> <li>Delegated bodies under Official Control Regulation 2017/625</li> <li>Notified Bodies tasked with conformity assessment</li> </ul>	<ul style="list-style-type: none"> <li>Migration testing rules</li> <li>Analytical methods</li> <li>Further development of test methods and technical standards as required</li> </ul>

The study team was tasked with tackling the difficulties in the transfer of information along the FCM production chain, resulting in difficulties for industry to ensure and demonstrate compliance and for Member States to undertake controls, through the development of an IT system.



# The Study supports an IT infrastructure for information exchange and verification of compliance

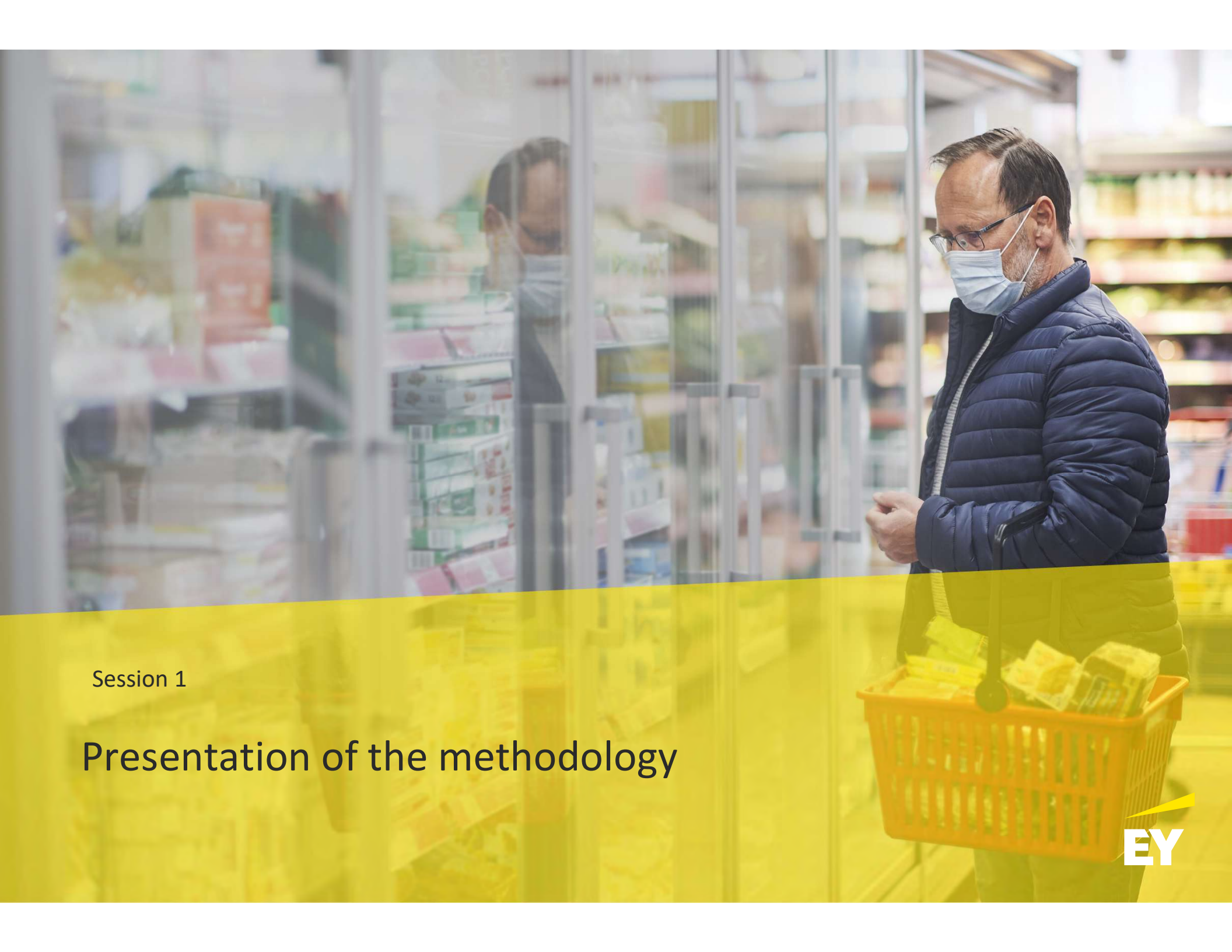
## Overall Objective

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 through the IT system.



Session 1

# Presentation of the methodology

# The approach to the study

## Study design

- ▶ Exploratory interviews
- ▶ Desk research
- ▶ Elaboration of the methodological approach
- ▶ Inception report

## Data collection

- ▶ Analysis of feedbacks to IIA and PC
- ▶ Written questionnaires for MS
- ▶ Online survey for industries
- ▶ Targeted interviews
- ▶ Case studies

## Elaboration of policy options

- ▶ Development of policy options
- ▶ Preliminary identification of impacts
- ▶ Initial report on options

## Validation of policy options

- ▶ Ah-hoc meetings with EC
- ▶ Second round of interviews with stakeholders
- ▶ Refinement of policy options

## Assessment of impacts

- ▶ Assessment of impacts of policy options

## Implementation pathways

- ▶ Identification of preconditions and steps towards implementation
- ▶ Draft final report

## Validation of findings and finalisation

- ▶ Stakeholder validation workshop
- ▶ Final report

# Data collection

01

## Desk research

- Legislative texts
- Evaluation of the FCM legislation
- Audit reports
- Research articles
- Industry reports
- Industry guidelines

02

## Surveys

- 21 National Competent Authorities and 6 National Reference Laboratories answered the written questionnaires
- 355 industry representatives answered the online questionnaire (of which 170 were retained – 10% response threshold)

03

## Interviews

- 25 interviews with EU industry associations
- 14 interviews with EU MS and Norway
- 9 interviews with EC, agencies and IT systems
- 3 interviews with similar IT systems (IMDS, Digital Product Passport, EMVO)

04

## EC Consultations

- Analysis of 302 feedbacks to Inception Impact Assessment (IIA)
- Analysis of 609 responses to the Public Consultation (PC)

05

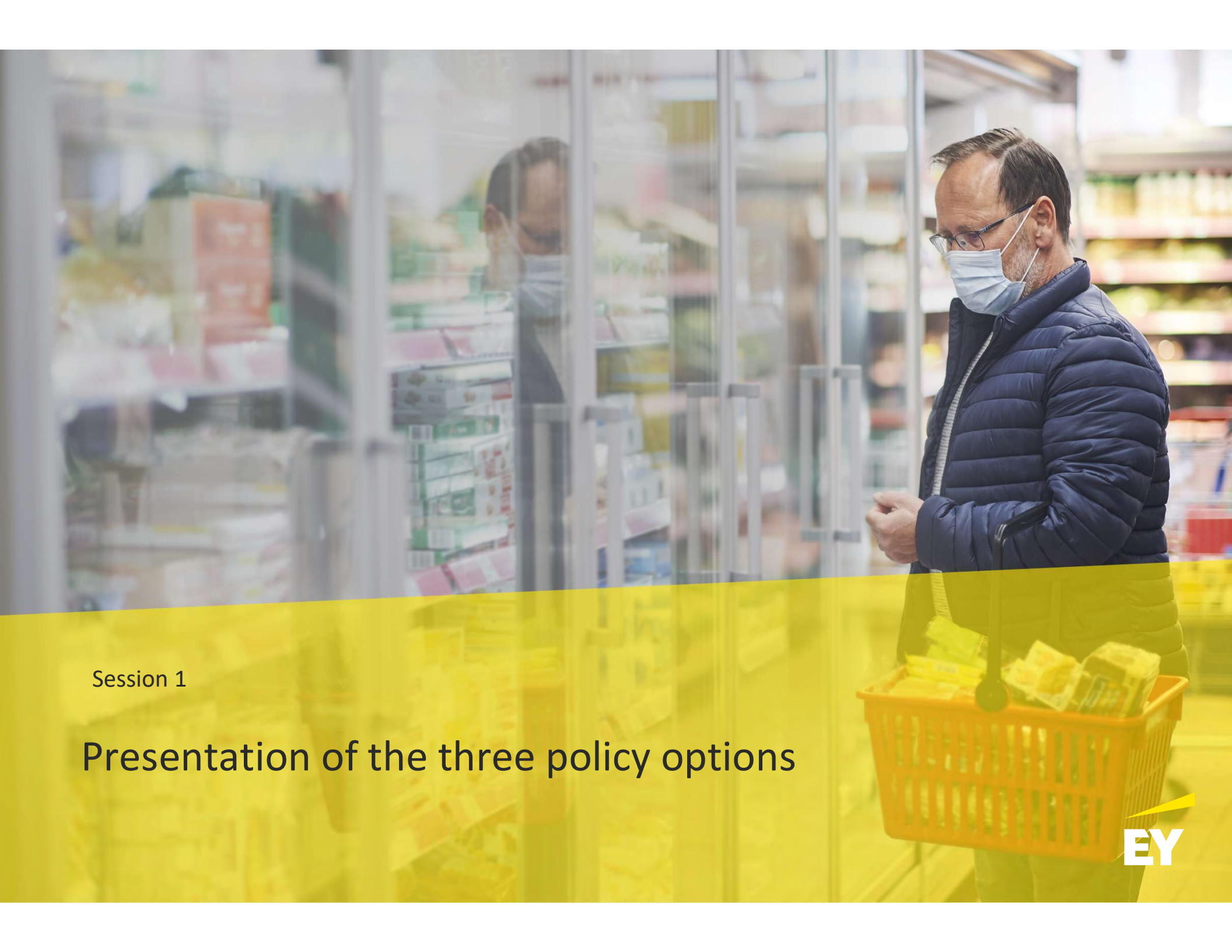
## Case studies

- 3 industry case studies (metal packaging, plastics and wooden FCMs) with use case scenarios
- 5 case studies on IT infrastructures for information exchange

06

EY Knowledge Management





Session 1

## Presentation of the three policy options

# Addressing insufficient information exchange in the supply chain through an IT system

## The problem

Inability of supply chain actors and competent authorities in Member States to ascertain compliance and ensure safety in Food Contact Materials (FCMs) due to a lack of sufficient information relating to the safety of FCMs throughout the production chain.

Actors participating in a certain FCM's production chain who introduce a tier 3 substance do not adequately assess the safety of that substance or provide necessary information about its safe use and presence. This is due to limited access to pre-existing information on that substance, and the information they generate is not easily accessible to other relevant parties

FCM producers **lack complete information** on the identity and amount of all substances present in their products, and the quantities they can present and migrate which restricts their ability to exclude possible presence of tier 1 substances below a predetermined limit. Their knowledge gaps are not being sufficiently filled by information from earlier stages of the FCM production chain, hence increasing the risk

**Official control bodies and enforcement authorities cannot quickly identify and understand the safety of final FCM articles due to a lack of access to information generated/missing information**

# Addressing insufficient information exchange in the supply chain through an IT system

In this context, the European Commission proposed creating an IT system to support the exchange of information and verification of compliance in the FCM supply chain. The system aims to solve these problems by increasing transparency and facilitating more effective regulation and oversight

## Three types of IT systems were proposed:

- ▶ Centralized IT system with an EU body responsible for management and decision making
- ▶ Decentralized IT systems with Member States responsible for management and decision making
- ▶ Decentralized IT systems with businesses responsible for management and decision making

Specific Objective 1: Allow for easy access to information on the composition and safety of FCMs

Specific Objective 2: Allow for easy verification of compliance information and enforcement

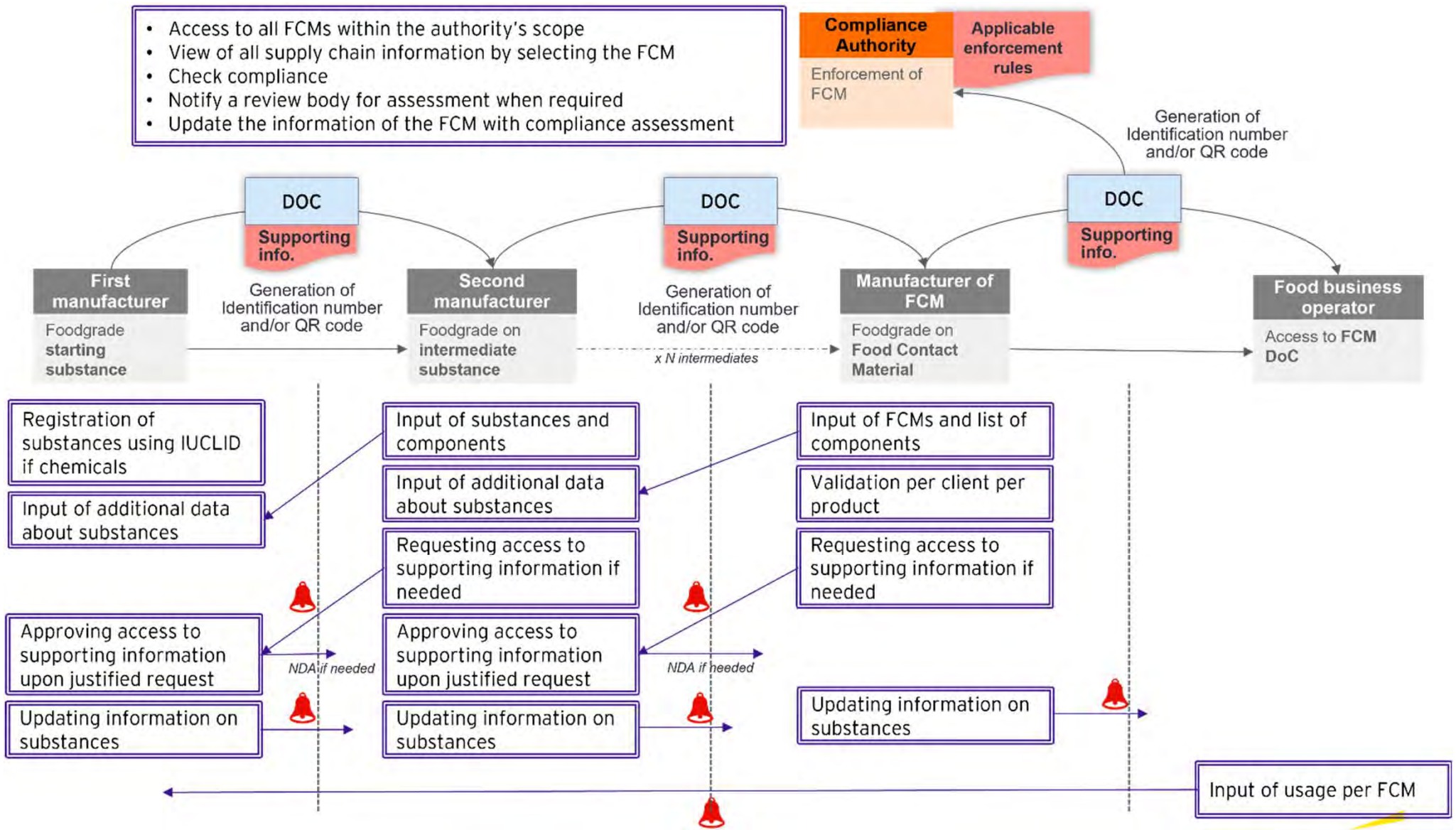


# Overview of an example of the functioning of the IT system

- Access to all FCMs within the authority's scope
- View of all supply chain information by selecting the FCM
- Check compliance
- Notify a review body for assessment when required
- Update the information of the FCM with compliance assessment

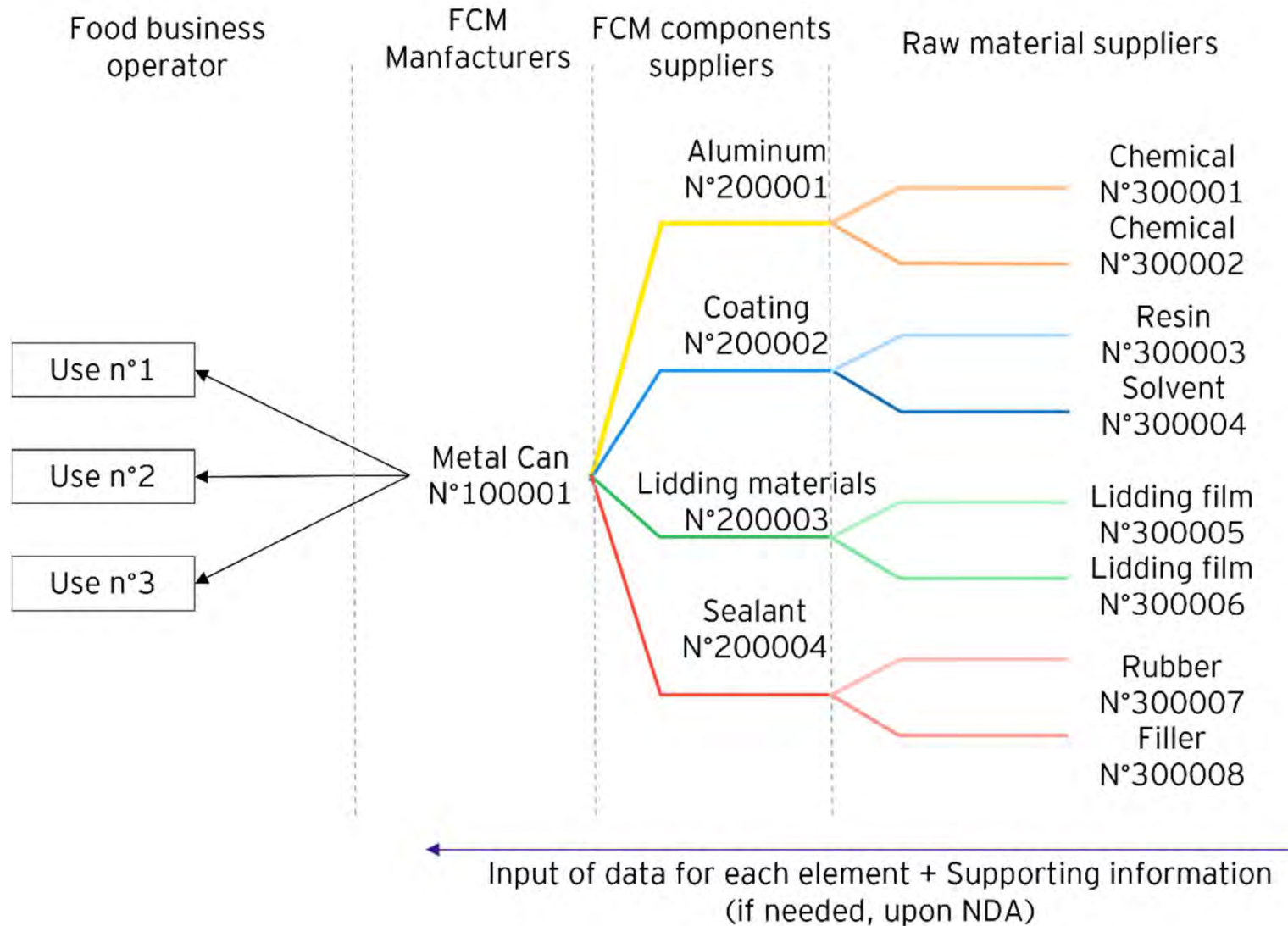
**Compliance Authority**  
Enforcement of FCM

**Applicable enforcement rules**





# Overview of an example of the functioning of the IT system

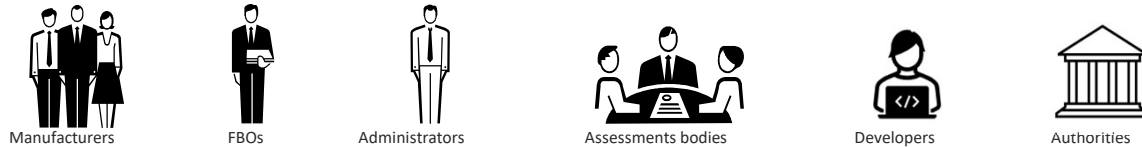


# Overview of an example of the functioning of the IT system

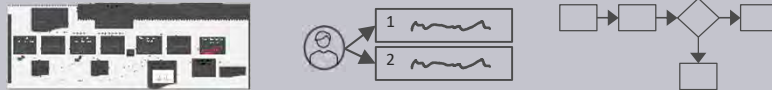
Browse	Material Card (name of material)
<ul style="list-style-type: none"> <li>Food contact material           <ul style="list-style-type: none"> <li>• Component 1               <ul style="list-style-type: none"> <li>• <b>Component 11</b> <ul style="list-style-type: none"> <li>• Raw material 1</li> <li>• Raw material 2</li> </ul> </li> <li>• Component 12</li> </ul> </li> <li>• Component 2</li> <li>• Component 3</li> <li>• ...</li> </ul> </li> </ul>	Business information
	Name of company, Identification number, Address, Country, Contact
	Material information
	Material name & description List of components : <ul style="list-style-type: none"> <li>- Type of component</li> <li>- Name of component</li> <li>- Description</li> <li>- Identification number</li> <li>- Link to « Material Card »</li> </ul>
	Risk assessment information
Certifications Test results Migration information	
	Compliance information
Date of verification of compliance NCA conducting the verification of compliance Results and comments on verification of compliance	
	Other
Supporting information and documents Other comments	

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

## Detailed layers composing the business architecture and the technology architecture



Define macro processes, user stories and business process decomposition



SaaS

- ▶ Business Application Services
- ▶ Service Catalog
- ▶ Information exchange services
- ▶ UX/UI Services
- ▶ Alerts and Notification Services
- ▶ Reporting Services
- ▶ Assessments services
- ▶ Administrators services
- ▶ Mobile Applications
- ▶ Users On-boarding

Application architecture

PaaS



Platform and Data architecture

IaaS



Infrastructure architecture

Business perspective

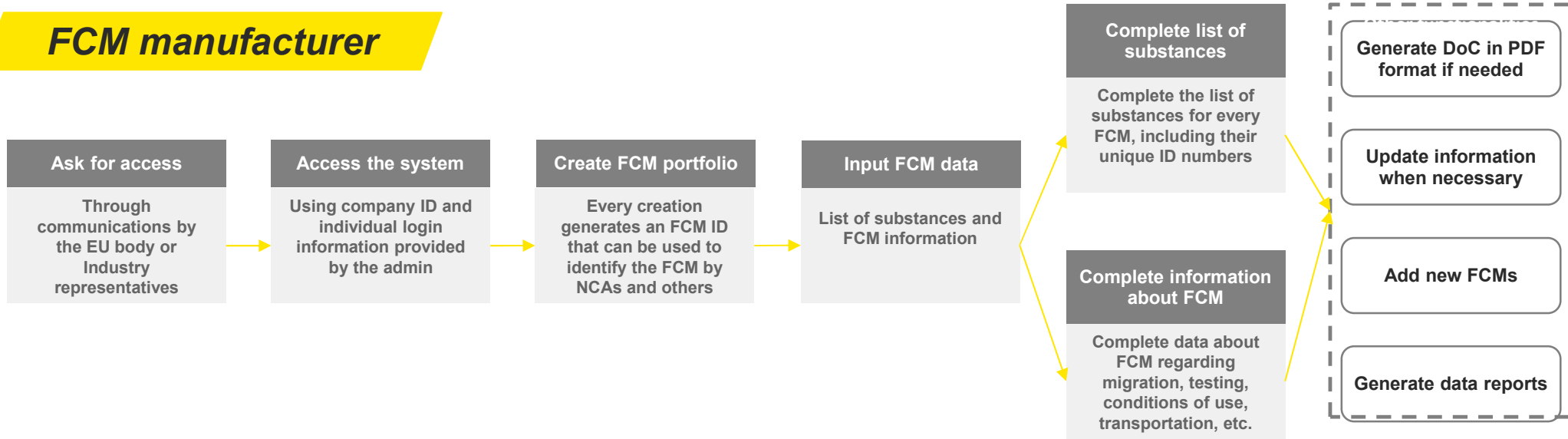
Technology perspective

## Key Results

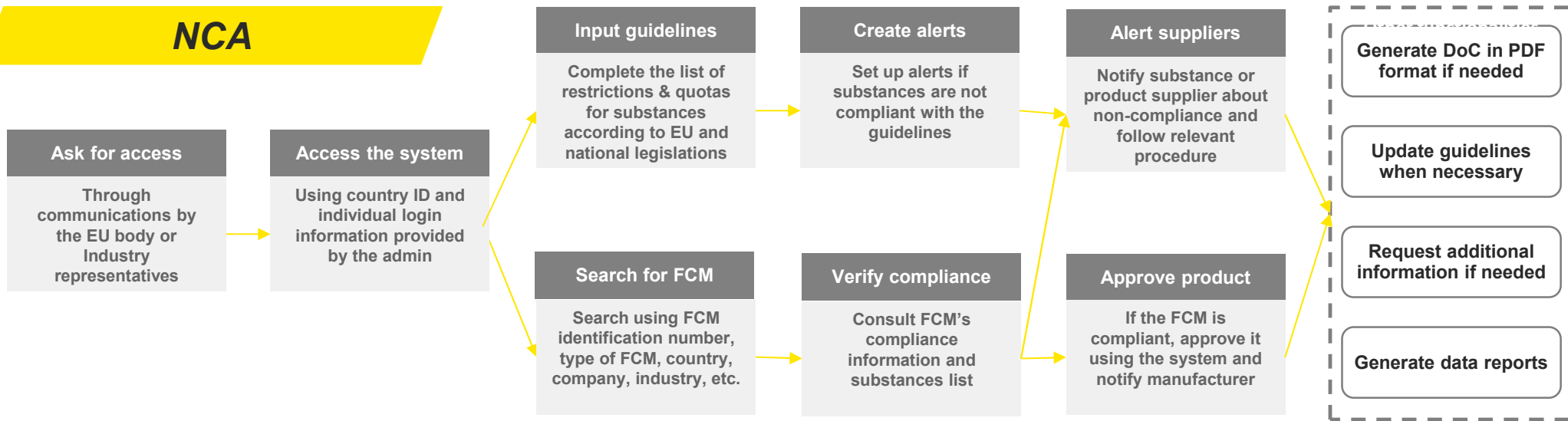
- First layer : mapping out target macro-processes and requirements in terms of information exchange and evaluation to be included in an IT system.
- Second layer : application and more broader technologies
- Third layer : data architecture and functioning of the platform
- Fourth layer : hardware and infrastructure

# Business Architecture - examples

## FCM manufacturer



## NCA





# Technology Architecture - examples



## Application Architecture

### Notification system:

- Notifications would be triggered by the input of new data, its modification, its updates, its compliance verification, etc.

### UX/UI:

- The platform would need to be user friendly. This includes the authentication portal, navigation, menus, buttons, etc.



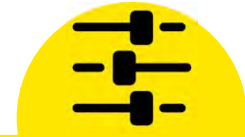
## Platform and data Architecture

### Access to the system:

- Private and profile-based access

### Data input:

- The data input in the system can come from different sources:
  - Manual input of data
  - Data retrieval from interconnected company platforms
  - Data retrieval from interconnected IT system (for chemicals for example)
  - Initial data uploaded within the system (from already existing data bases of substances and materials)



## Infrastructure Architecture

### Hardware:

- Servers must be located within the EU.
- Depending on the body responsible for decision making (policy option), the servers would be located either within the country responsible for the system, the location chosen by the industry or the location chosen by the EU-body.

### Security:

- Back-up and recovery
- Firewalls
- Encryption

# Introducing the policy options

The study team was tasked with developing three policy options to support an IT infrastructure for information exchange and verification of compliance

		Governance	
		Centralized	Decentralized
IT	Centralized	<p><u>Policy Option 1</u> A unique <b>EU-level</b> database used by all stakeholders in the FCM supply chain, and managed by an <b>EU entity</b>.</p>	<p><u>Policy Option 2A</u> Decision-making is shared between <b>Member State</b> each of them manages their <b>own database</b>, which are connected to central database at the EU level.</p>
	Decentralized		<p><u>Policy Option 2B</u> Decision-making is shared between <b>Member State</b> each of them manages their <b>own database</b> for the country / FCM activity they oversee, with <b>interoperability</b> between systems.</p> <p><u>Policy Option 3</u> Decision-making is shared between <b>Industries</b> each of them manages their <b>own database</b>.</p>

# Distinguishing features of policy options

## Common principles

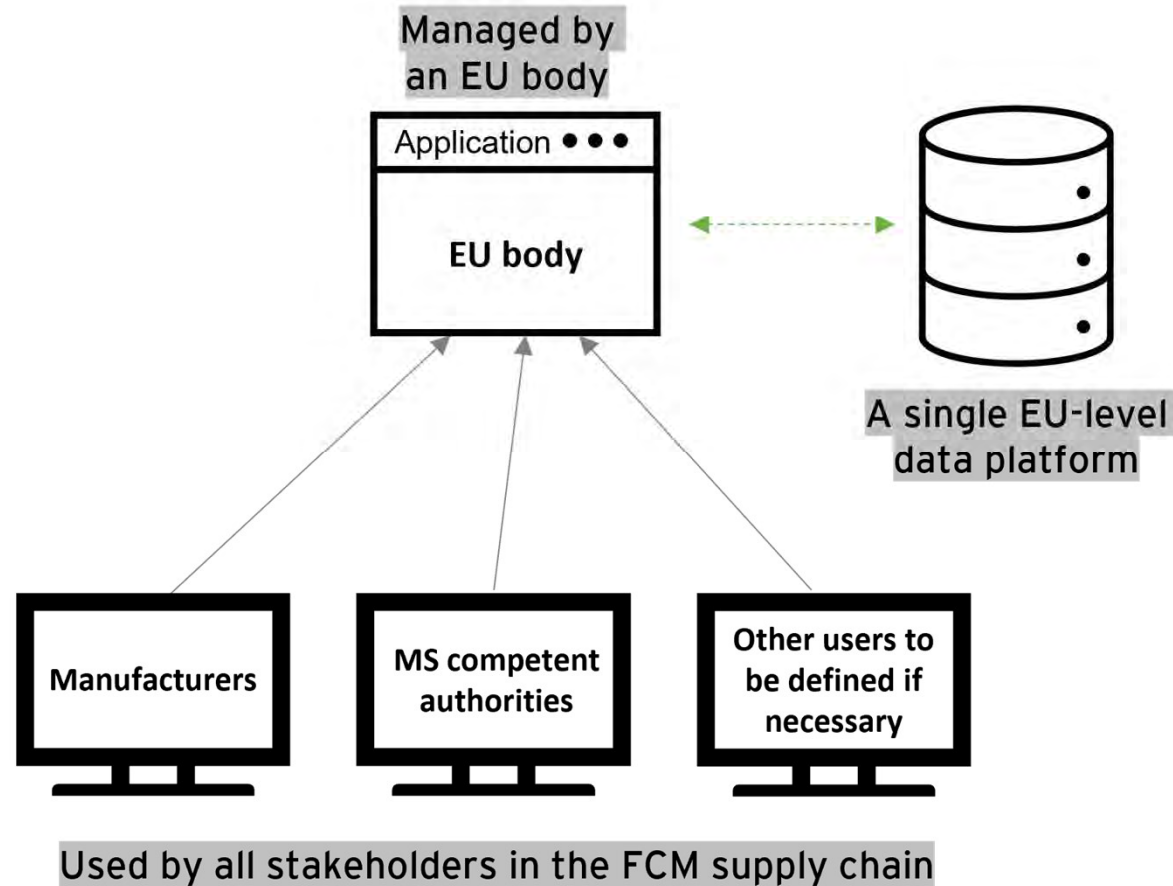
- ▶ European Commission – sets the guidelines for all IT systems
- ▶ The actor who exercises the governance of the system, not only sets up the system but is also the administrator of the same. It is in charge of the daily management of the system (e.g., providing access, application of guidelines, alerts etc.).
- ▶ Manufacturers, raw material and intermediate suppliers, non-EU suppliers (through importers or local subsidiaries), food business operators have access to the system and are able to input data about their substances or products as well as to consult data to carry out their compliance work. These actors can request additional or missing information to upstream or downstream actors.
- ▶ National Competent Authorities (NCAs) have access to data on FCMs and substances immediately and at every step of the way (including supporting documentation) in each system. They are also able to request additional information previous/during/after inspections.

## Main differences

- ▶ The governance of each system differs. In Policy Option 1, an EU body exercises the governance of the system, whereas in Policy Option 2 and 3 it is Member States and industries (industry association or clusters of industries) respectively.
- ▶ In Policy Option 2A and B, a body needs to be identified to manage the EU-level data hub or the interoperability between national systems.
- ▶ The location of databases differs from one option to another. In Policy Option 1, there is only one central database that is linked to an application which is used by all actors in the supply chain; in Policy Option 2, there is one database for each Member State which are used by national actors of the supply chain and interconnected to other national databases either through an EU-data hub or are made interoperable; in Policy Option 3 the databases are as many as the number of industry associations or clusters of industries that set them up and are used by actors doing business within a specific industry across Member States

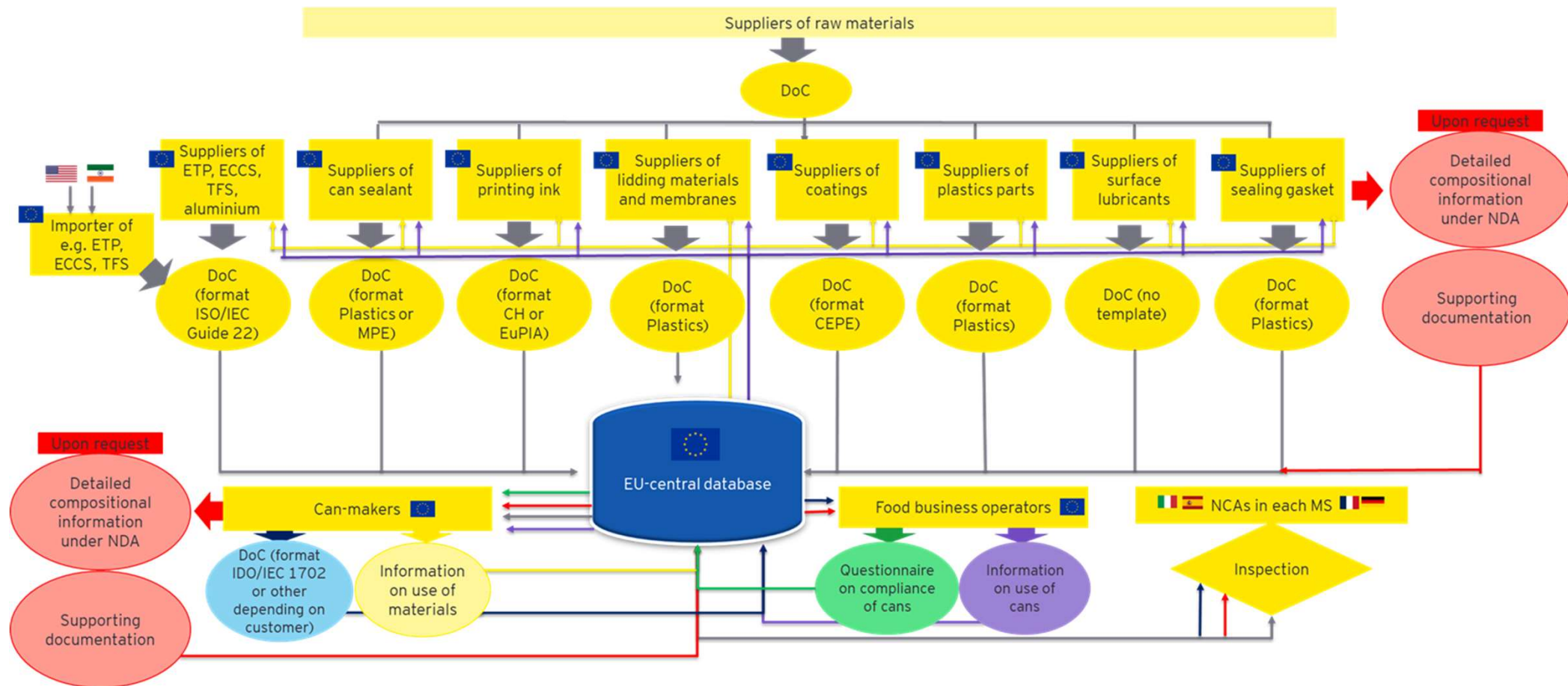
# Policy option 1: Centralized EU IT system

Centralized IT system managed by an EU body with central data platform linked to a centralized application at EU level\*



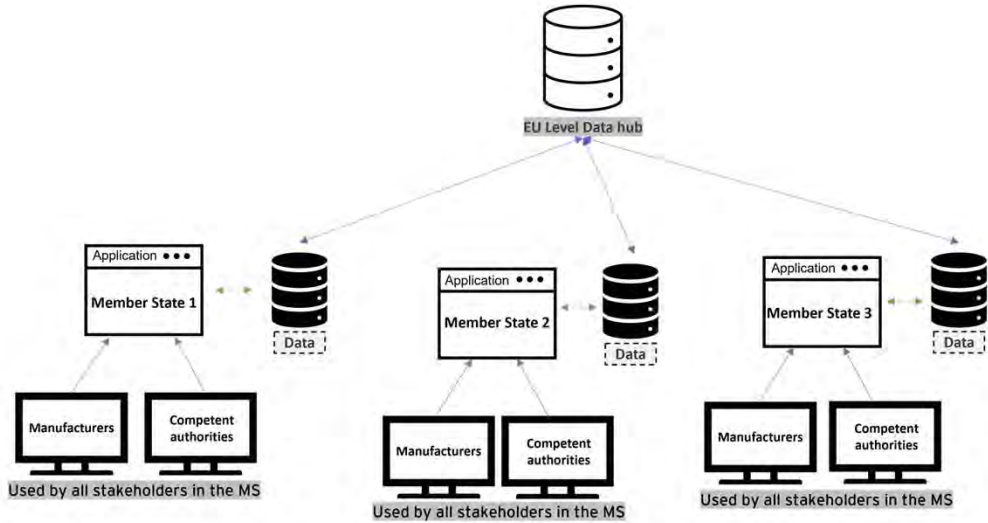


# Use case application of policy option 1 to the metal packaging industry

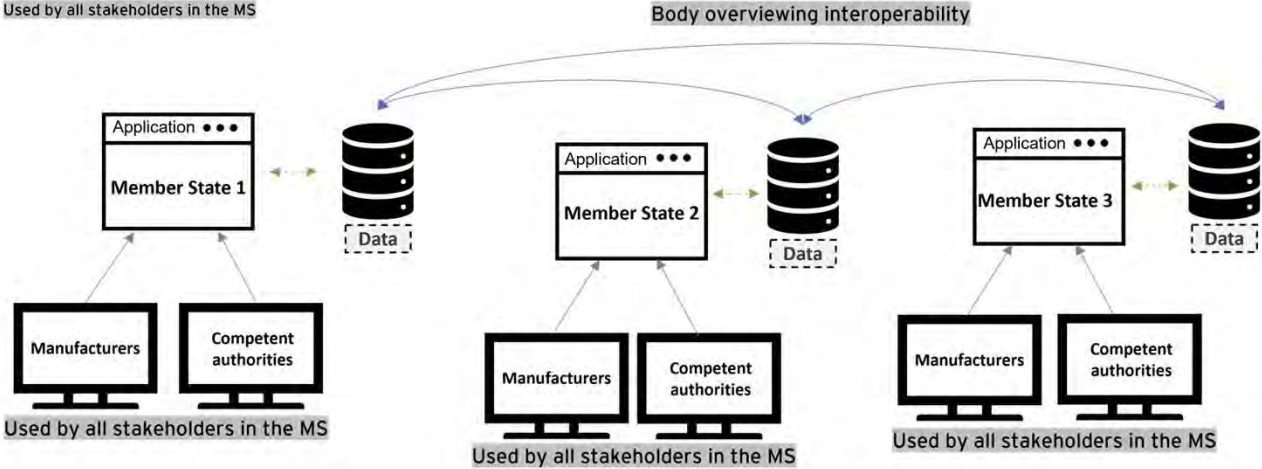


# Policy option 2: Decentralized MS-level IT systems

## PO2A: Decentralized Member States-managed IT system with EU level data hub\*

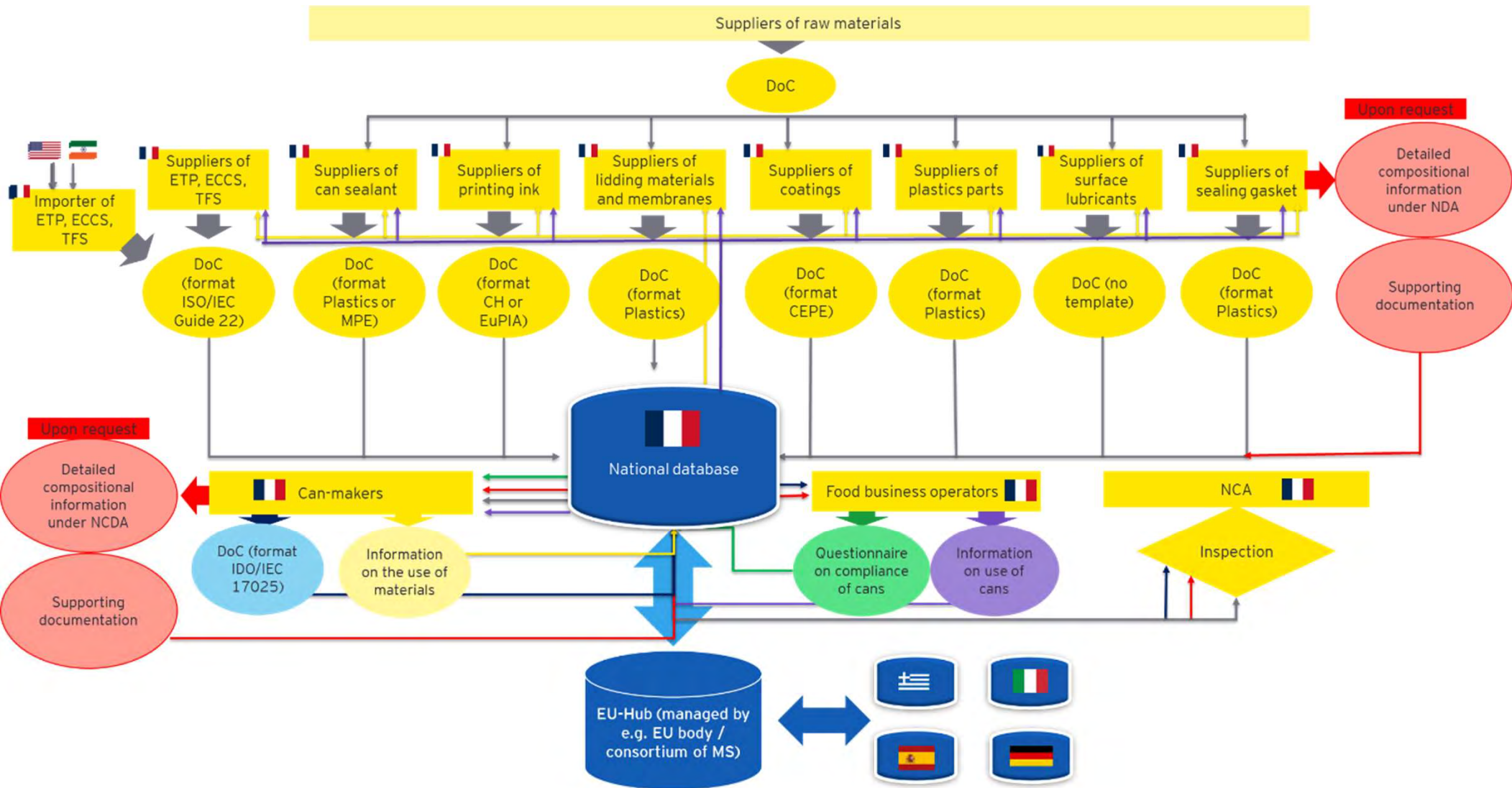


## PO2B: Interoperable Member States-managed decentralized IT system

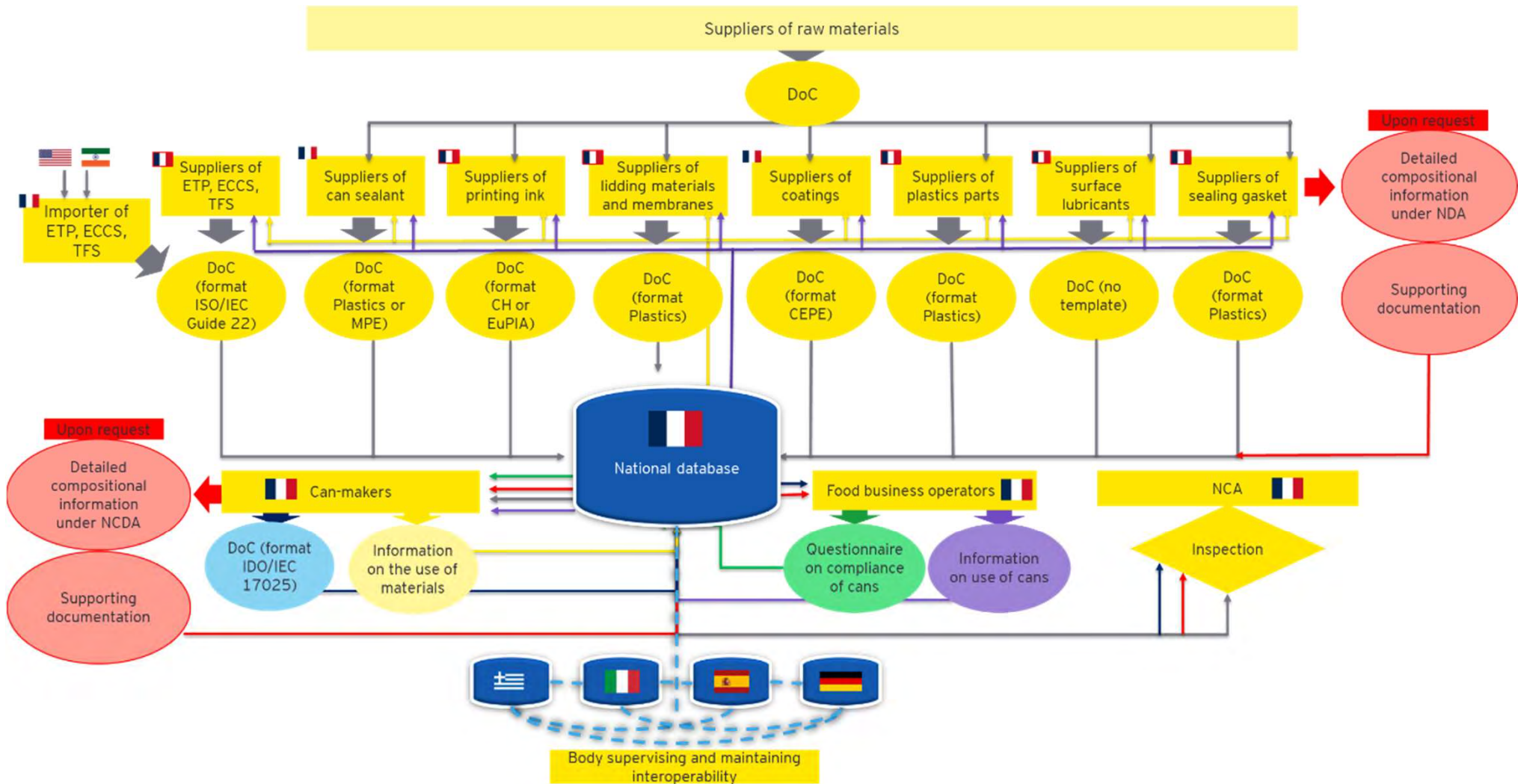


\*The IT architecture for this system is inspired by EMVS

# Use case application of policy option 2A to the metal packaging industry



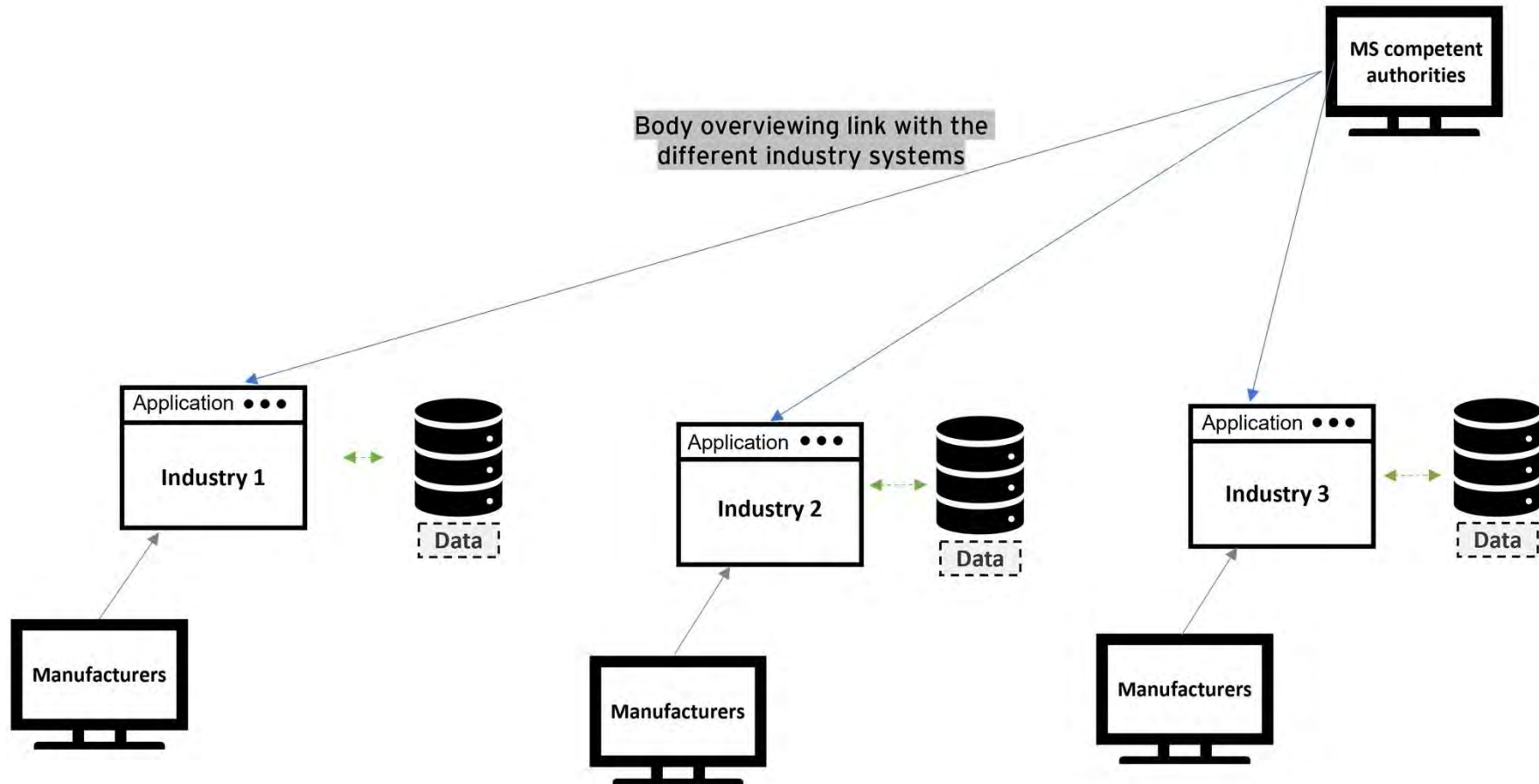
# Use case application of policy option 2B to the metal packaging industry



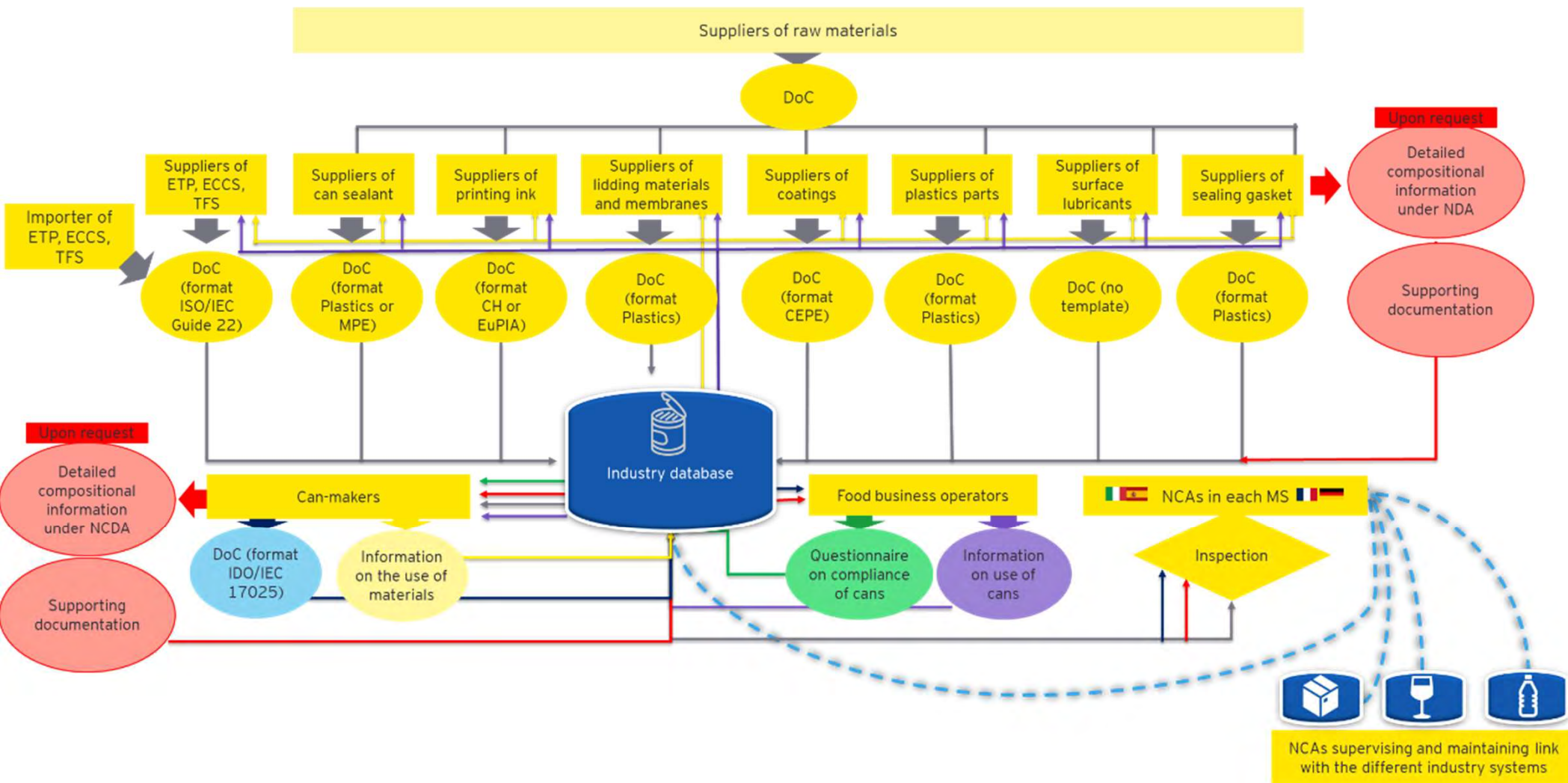


# Policy option 3: Decentralized industry-level systems

Decentralized IT system where management and decision making are in the hands of industries\*



# Use case application of policy option 3 to the metal packaging industry



# Recap on policy options

## Policy Option 1: Centralized EU-level IT system

- ▶ Single database at the EU level which is used by all actors of the supply chain and NCAs.
- ▶ An EU-body sets up the system and manages it within the guidelines of the EU Commission.
- ▶ Actors within the EU interact with the EU-level database, including NCAs

## Policy Option 2: Decentralized MS-level IT systems

- ▶ Multiple national databases
- ▶ Communication among databases is ensured by an EU data hub or by interoperability between databases
- ▶ Each MS has to bear responsibility for setting up their own database and manage it according to EC's guidelines
- ▶ Actors within each MS interact with their national database, including NCAs who have access to information across MS

## Policy Option 3: Decentralized industry-level IT systems

- ▶ Multiple industry-specific databases
- ▶ Industry associations or consortia of industries set up their own database which does not communicate with other industry-led databases
- ▶ Actors doing business with specific industries interact with the relative industry-level databases
- ▶ NCAs access all single industry-led databases



Session 2

## Presentation of the assessment of impacts



# Assessment of the most significant impacts of policy options

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## Approach

- (i) Qualitative analysis of the options and their impacts based on the data collection and EY experts' analysis;**
- (ii) The first assessment criteria considered is effectiveness of the policy options to achieve the specific objectives;**
- (iii) Other assessment criteria concerned "technical" impacts specific to IT systems associated with the options.**

# Assessment of effectiveness of policy options to the objectives of the revision

## General objectives

- ▶ Ensure food safety and public health
- ▶ Guarantee the effective functioning of the internal market
- ▶ Promote sustainability

## Specific objectives

- ▶ SO1: Allow for easy access to information on the composition and safety of FCMs
- ▶ SO2: Allow for easy verification of compliance information and enforcement

## Results of the assessment of effectiveness

- (i) All policy options are in principle effective to address the aforementioned specific objectives;
- (ii) Policy Option 1 results as the most effective in achieving both specific objectives as it provides the most streamlined and centralised approach offering a clear path for improved access to information and compliance verification;
- (iii) Policy Option 2 results as less effective than PO1 because it introduces potential interoperability issues, increased costs for MS and the likelihood of disparities in funding and IT system development possibly hindering easy and harmonised access and verification of information across the EU;
- (iv) Policy Option 3 results as the least effective as it relies heavily on industry collaboration which may not ensure comprehensive compliance data and could pose challenges in ensuring complete and accurate information

# Assessment of technical impacts of policy options

Several criteria have been considered and assessed qualitatively to identify technical impacts related to the implementation and the run of each IT system, including the following:

## Implementation

- ▶ Data Management
- ▶ Governance complexity
- ▶ Inequalities
- ▶ Global adaptability
- ▶ Local adaptability

## Run

- ▶ Consolidation
- ▶ Resilience
- ▶ Data protection
- ▶ Governance complexity
- ▶ Cost efficiency
- ▶ Innovation
- ▶ Global adaptability
- ▶ Local adaptability

The next slide presents an overview of the assessment for 3 criteria each for the implementation and the run of the IT systems.

# Assessment of technical impacts of policy options

IMPLEMENTATION	Policy Option 1	Policy Option 2A	Policy Option 2B	Policy Option 3
<b>Coordination effort</b>	+++ (low coordination efforts)	++ (moderate coordination efforts)	+ (high coordination efforts)	+ (high coordination efforts)
<b>Cost efficiency</b>	+++ (highly cost efficient)	+ (not cost-efficient)	++ (moderately cost efficient)	++ (moderately cost-efficient)
<b>Consolidation</b>	+++ (highly efficient data consolidation)	++ (moderately efficient data consolidation)	+ (least efficient data consolidation)	+ (least efficient data consolidation)

RUN	Policy Option 1	Policy Option 2A	Policy Option 2B	Policy Option 3
<b>Scalability</b>	+++ (highly scalable)	++ (moderately scalable)	++ (moderately scalable)	++ (moderately scalable)
<b>Data Management</b>	+++ (simple data management)	+ (complex data management)	+ (complex data management)	+ (complex data management)
<b>Service delivery</b>	++ (uniform but limited service delivery)	++ (specific but unequal service delivery)	++ (specific but unequal service delivery)	++ (specific but unequal service delivery)



# Assessment of technical impacts of policy options

From a technical point of view, the PO1 is the more efficient solution in terms of simplicity and optimization of efforts. However, three main analysis dimensions must be considered:

## Implementation

PO1 will require an **important effort** and traction to initiate and define the system and a **very high front value to engage the investment**.

On the opposite, the first implementation steps of the other POs will require **setting up smaller systems** (at country level or industry level). The first **investments** will appear to be **significantly lower** and each instance will be able to **start at their own rhythm**.

The counterpart will be that it will be **more difficult to project a deadline** at which the system would be fully operational.

## Customization

PO1 will be halfway between the need for the system to have as many functionalities to **satisfy every country and industry**, but also for them to **fit in a single model**.

The systems under PO2 and PO3 would have **customized services**, fitting to local processes and specificities. It could create a **better acceptance of the system** and more personalized services.

However, it would make **data reconciliation more complex** and make it **harder to ensure the full vision on the data collection** throughout the systems, especially for NCAs.

## Cost efficiency

The PO1 will require a **bigger initial investment**.

However, the other POs will lose the initial advantage because of the **potential redundancy of work on the different systems** and the **effort for reconciliation**.

PO2A would **combine both disadvantages** with the cost of building a central system and the cost for reconciliation.

However, it would be the **best compromise** between the quality of service and the capacity of reconciliation.

# Qualitative estimation of the cost burden of each policy option

## FCM IT System costs will vary according to data volumes

- (i) For Policy Option 1, all FCM data is stored in a single data platform, processing significant volume of data, with no duplication;
- (ii) For Policy Option 2A, FCM data is stored in Member State-specific platforms, reducing individual data volumes but duplicated in a central data-hub;
- (iii) For Policy Option 2B, FCM data is stored in Member State-specific platforms, reducing individual data volumes, with no duplication;
- (iv) For Policy Option 3, FCM data is stored in Industry-specific platforms. Duplication occurs across industries that share suppliers, increasing data volumes

	Policy Option 1	Policy Option 2A	Policy Option 2B	Policy Option 3
<b>Global costs</b>	+++	+	+	+
<b>Local costs</b>	+ Per MS/Industry	++ Per Member State	+++ Per Member State	+++ Per Industry
<b>Coordination costs</b>	+	+++	++	++

# Results of assessment of impacts

## Policy Option 1: Centralized EU-level IT system

- ▶ Implementation: Involves relatively low coordination efforts, making it cost-efficient and straightforward to manage. It ensures highly efficient data consolidation, simple data management, but is marked by complex governance due to diverse stakeholder needs, low global adaptability and potential inequalities.
- ▶ Run: High consolidation efficiency, scalability, simple data management, high control over data protection, simple governance, cost efficiency, limited room for innovation and high global adaptability, but low local adaptability.

## Policy Option 2B: Decentralized MS-level IT systems with interoperability

- ▶ Implementation: Similar to PO2a but with coordination efforts likely to rise due to the need to ensure interoperability. It's additionally perceived as less cost-efficient, equal in terms of data management, but less adaptable globally.
- ▶ Run: Slightly less efficient in consolidation than PO2a, moderately scalable, complex data management, variable service delivery, high resilience, moderate control over data protection and governance complexity, less cost efficient, greater prospects for innovation, but less global and high local adaptability.

## Policy Option 2A: Decentralized MS-level IT systems with EU-data hub

- ▶ Implementation: Moderate coordination efforts and cost-efficiency, slightly complex data consolidation and management, complex governance due to sharing decision-making among member states, potential for moderate inequalities, and moderate global and local adaptability.
- ▶ Run: Moderately efficient at data consolidation, moderately scalable, complex data management, variable service delivery, high resilience, moderate control over data protection, complex governance, moderate cost efficiency, moderate innovation potential, and moderate global and high local adaptability.

## Policy Option 3: Decentralised industry-level IT systems

- ▶ Implementation: High coordination efforts, moderate cost-efficiency, inefficient data consolidation, complex data management, highly complex governance, potential for high inequalities, and low global adaptability but high local adaptability.
- ▶ Run: Inefficient data consolidation, variable scalability, complex data management and governance, low cost efficiency, potential for unequal innovation, and low global adaptability but high local adaptability.



Session 2

## Discussion on assessment of impacts

## Discussion on policy options

Which policy option would you support?



**Mentimeter**

**For those online: please participate to the poll in the the Teams chat**

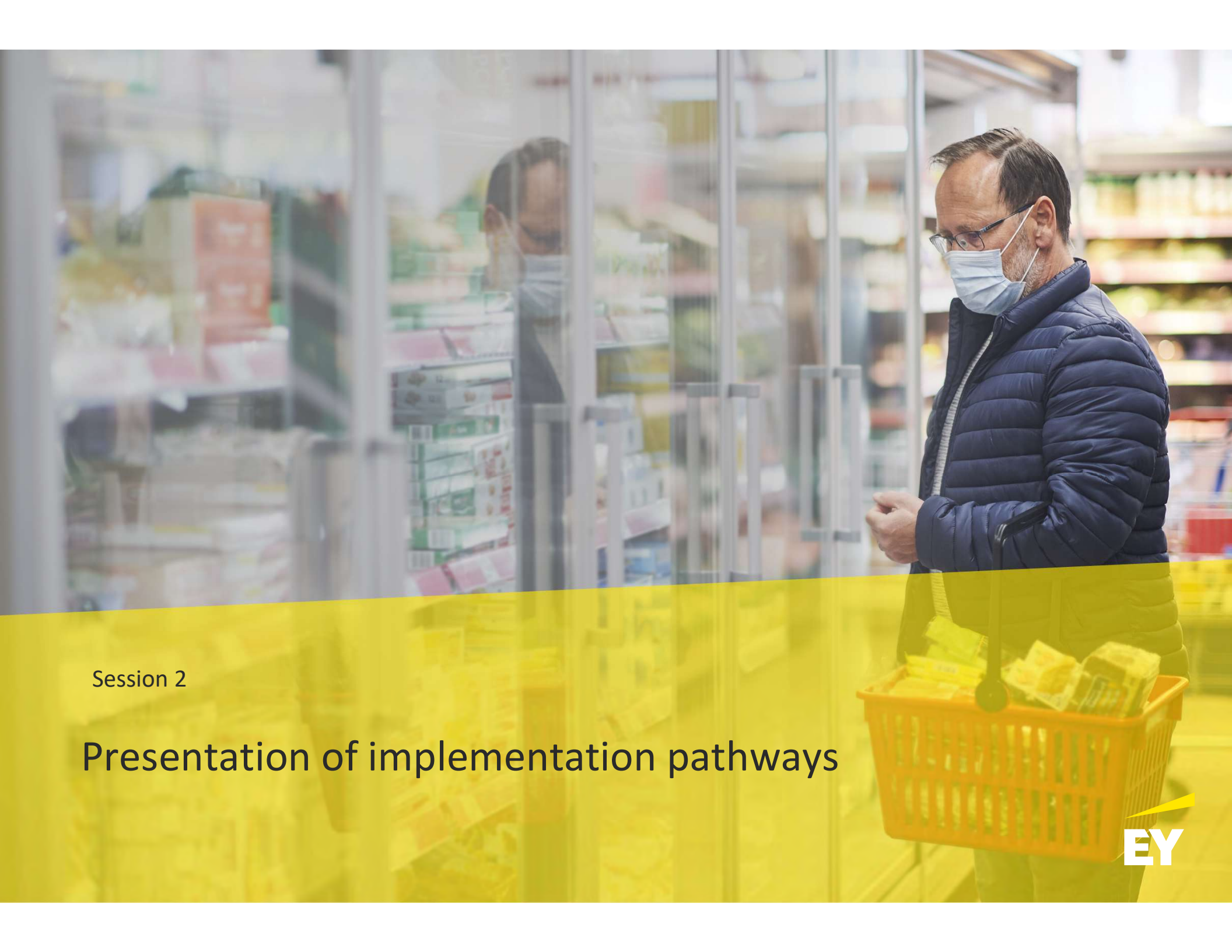


## Discussion on policy options

Can you mention any other impacts that weren't yet identified ?



**For those online: please participate to the poll in the the Teams chat**

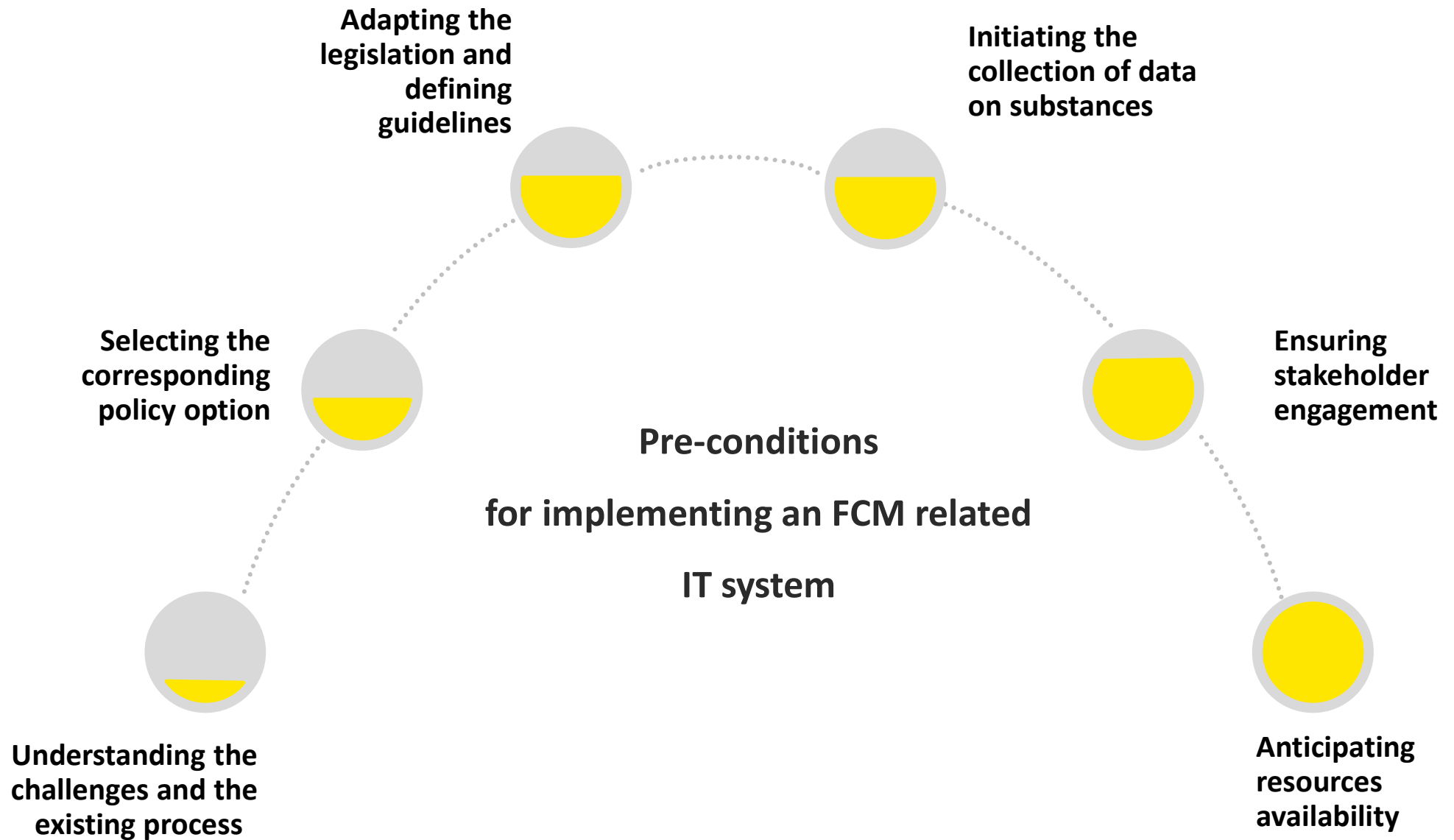


Session 2

## Presentation of implementation pathways

# Implementation of an FCM related IT system

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# Implementation of an FCM related IT system

## Implementation phases of the FCM IT system

### Discover

Understand FCM context and needs

### Design

Define the business processes and technology

### Develop

Develop and test the system

### Deploy

Implement the system

### Maintain

Check effectiveness and ensure maintenance

# Implementation of an FCM related IT system

## Implementation phases of the FCM IT system

### Discover

#### Understand FCM context and needs

Use insight from the study on FCMs to :

- get to know the stakeholders,
- be aware of their various needs,
- understand the stakes of the FCM legislation,
- define the operational objectives and KPIs of the IT

system ;

- plan the different milestones of the project ;
- Evaluate the impacts following the assessment.

#### Outcomes

A project plan outlining the context and scope of the project, objectives of the IT system and implementation process including a timeline, training, resources required for each phase, allocated budget and change management approach.

Request for proposal addressed to a selection of online platform editors and integrators.

Regulatory guidelines either specific to FCMs or to data security and confidentiality.

#### Challenges

Bringing together all relevant stakeholders and making sure that everyone is align and on board.



Project team



Future users



Authorities



# Implementation of an FCM related IT system

## Implementation phases of the FCM IT system

### Design

#### Define the business processes and technology

Based on the recommendations, this step requires to choose the technological solution to develop the IT system.

Simultaneously, the business processes must be reviewed and validated by the different future users.

The processes should be exhaustive and include all possible scenarios of how the system will be used. Technical specifications must be defined.

#### Outcomes

Software editor: provide documentation and access to their platform for developers to work on.

Technical and functional specifications for the IT system

These specifications must include the system guidelines defined by authorities.

#### Challenges

Ensuring the exhaustivity of the processes and their validation by all stakeholders.

Ensuring the availability of qualified resources.



Project team



Dev' team



Future users



Editor



# Implementation of an FCM related IT system

## Implementation phases of the FCM IT system

### Develop

#### Develop and test the system

The architecture of the system would be defined following the chosen policy option. The project can be set up following an Agile framework in order to proceed with iterations and test as you go. A pre-production environment is crucial

for such step. A training plan must be defined to support the implementation and avoid resistance to change regarding the IT system.

#### Outcomes

Responsibility assignment matrix (RACI) can be created to specific assign roles to each actor.

Depending on the chosen project framework, the deliverables can be different. For such project, the Scrum Agile framework would be the most suitable.

The system should be, as soon as the security requirement are sufficiently met, fed with available data on substances, collected before implementation.

A training plan to train users on how to enroll in and use the system, to have a better understanding of the solution.

#### Challenges

Ensuring strict security measures.

Ensuring coordination between the different systems and coordination in case of decentralized policy options.



Project team



Dev' team



Testers



Authorities



# Implementation of an FCM related IT system

## Implementation phases of the FCM IT system

### Deploy

#### Implement the system

Gradual implementation should be considered for such disruptive system. If PO1 is chosen, a planning must be defined, in which the scope of implementation will expand gradually, either depending on countries or industries.

For decentralized policy options, this will not be a significant issue. Change management must be taken into account all throughout. Providing training for future users must also be ensured for a smoother transition.

#### Outcomes

A pilot program can be rolled out to a limited number of end-users, that would identify and report issues to be fixed before official deployment.

The project team would have to create and look over a help desk and IT support, to receive user feedbacks and take the appropriate actions.

Training sessions can also be organized.

Gradual deployment can take place depending on the policy option.

#### Challenges

Ensuring a good allocation of budget and resources, without underestimation.

For PO2, ensuring coordination between deployment of the system, since there is an interdependence.



Project team



Dev' team



Future users



Admin



# Implementation of an FCM related IT system

## Implementation phases of the FCM IT system

### Maintain

#### Check effectiveness and ensure maintenance

Based on the KPIs and objectives defined in the framing phase, the system must be evaluated by every type of user in order to determine the extent to which the system meets their needs.

This feedback should enable the administrators to define their maintenance roadmap (eg. functionalities to be added/removed).

#### Outcomes

Monitoring key performance indicators of the system that were initially defined in the *Discover* phase and refined throughout the whole implementation.

The results and analysis of KPIs would have to be reported.

A continuous improvement plan is then launched in order to refine the product.

#### Challenges

Ensure access to training for all users.

Value feedback of users and take it into account for evolutions and maintenance.



Project team



Dev' team



Users



Admin





# Conclusion by DG SANTE





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