2nd Workshop on the Study supporting the Evaluation of the FCM legislation

Thon Hotel EU, Brussels
Monday 9 September 2019

Agenda

- Introduction
- Objectives and format
- Presentation approach and consultation strategy

- Discussion on preliminary findings
  - Session 1 – Effectiveness
  - Session 2 – Efficiency
  - Session 3 – Relevance and Coherence
  - Session 4 – EU added value + concluding comments

- Final remarks

Agenda

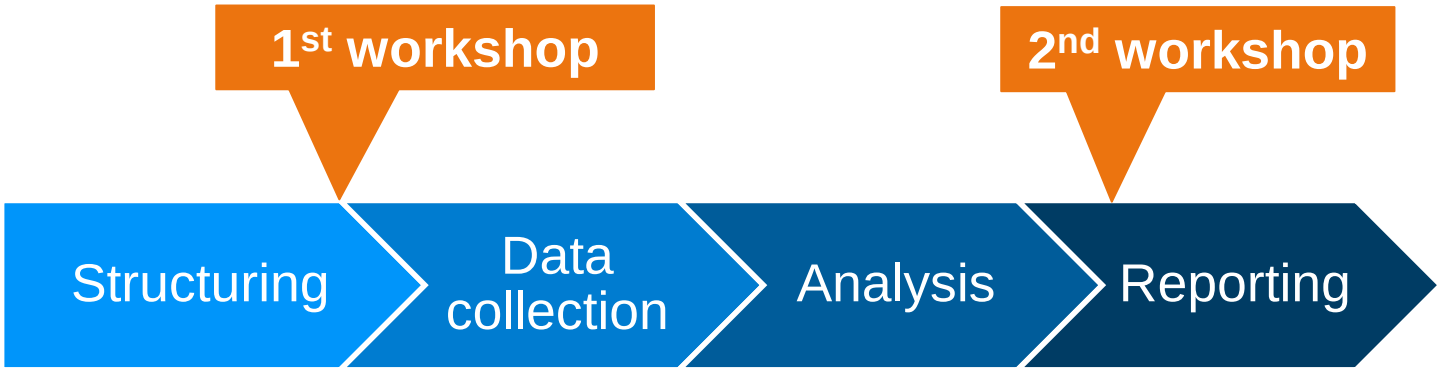
11h00 – 11h30: Tea and coffee break

12h30 to 13h30: Lunch buffet

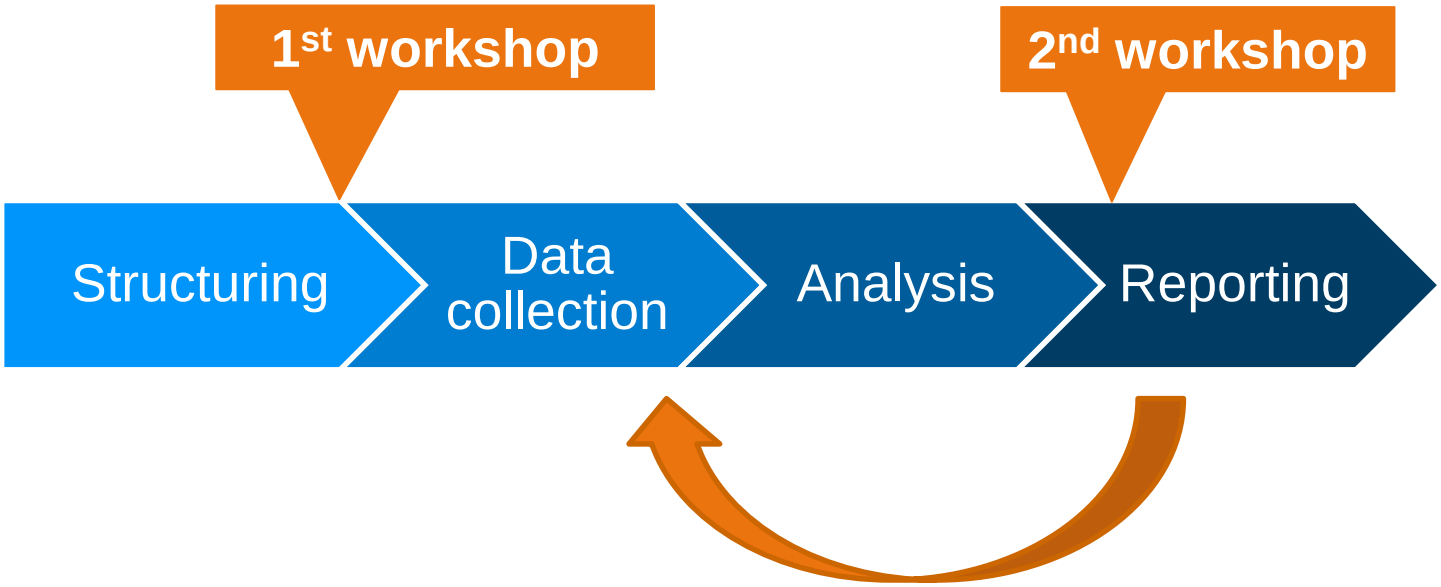
15h00 – 15h30: Tea and coffee break

17h30: End

..Where are we?


1st workshop
2nd workshop
Structuring
Data collection
Analysis
Reporting

..Why are we here?



Objectives and format

1) **Objectives: collect feedback and further evidence**
   - During the workshop
   - Also written contributions until 16 September

2) **Format**
   - 4 sessions
   - 3 steps per session
     - ❑ Presentation
     - ❑ Table discussion
     - ❑ Reporting

Table discussions and reporting

Table discussion

- Different findings discussed per table
- 1 rapporteur per table
- Rapporteurs complete the feedback document

Reporting

- All feedback documents will be collected
- Session 1 to 3: some rapporteurs speak
- Session 4: all rapporteurs speak
- Maximum 3 minutes per table

Feedback documents

Feedback Document – Session number ☐ **Table number** ☐

Evaluation question & key finding number	*Comments and supporting evidence*

EQ 7 (relevance) on evolving science and innovation

1. Regulation (EC) 1935/2004 does not provide sufficient flexibility when it comes to considering **new scientific knowledge** and **technological developments**

2. There is **no mechanism in place to prioritise** the handling of certain substances of health concern

3. It is unclear to what extent Regulation (EC) 1935/2004 stimulated **research and innovation**

Feedback documents - example

Feedback Document – Session number 3 **Table number** 14

Evaluation question & key finding number	*Comments and supporting evidence*
EQ7 Finding1	C= Disagreement that the Reg does not foresee periodic revision of specific measures E= Reg 10/2011 has been modified 13 times in 8 years

EQ 7 (relevance) on evolving science and innovation

1. Regulation (EC) 1935/2004 does not provide sufficient flexibility when it comes to considering **new scientific knowledge** and **technological developments**

2. There is **no mechanism in place to prioritise** the handling of certain substances of health concern

3. It is unclear to what extent Regulation (EC) 1935/2004 stimulated **research and innovation**

Feedback documents - example

Feedback Document – Session number 3 **Table number** 14

Evaluation question & key finding number	*Comments and supporting evidence*
EQ7 Finding3	C= Innovation: the regulation stimulated industry research for the development of safer materials E1= annual investment for the development of new FCM by the plastic industry increased by 5% since the entry into force of the Regulation (from X Mln to X Mln per year)

Feedback documents - example

Feedback Document – Session number 3 **Table number** 14

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Feedback documents - example

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Evaluation question & key finding number	*Comments and supporting evidence*
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EQ7 Finding3	C= Innovation: the regulation stimulated industry research for the development of safer materials E1= annual investment for the development of new FCM by the plastic industry increased by 5% since the entry into force of the Regulation (from X Mln to X Mln per year)
EQ7 Finding3	C= Innovation: the regulation does not stimulate industry investment in research in the EU E1= procedures in the EU are much longer and uncertain than in the USA. For example …

Table discussions and reporting

- 1 rapporteur complete the feedback document
- All feedback documents will be collected
- Reporting: maximum 3 minutes per table

+ *written contribution until 16 October*

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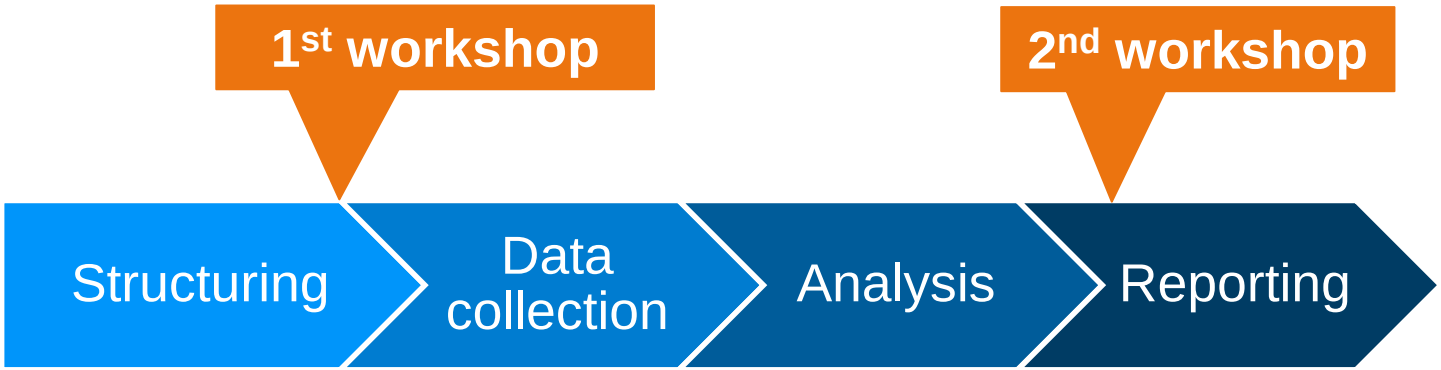
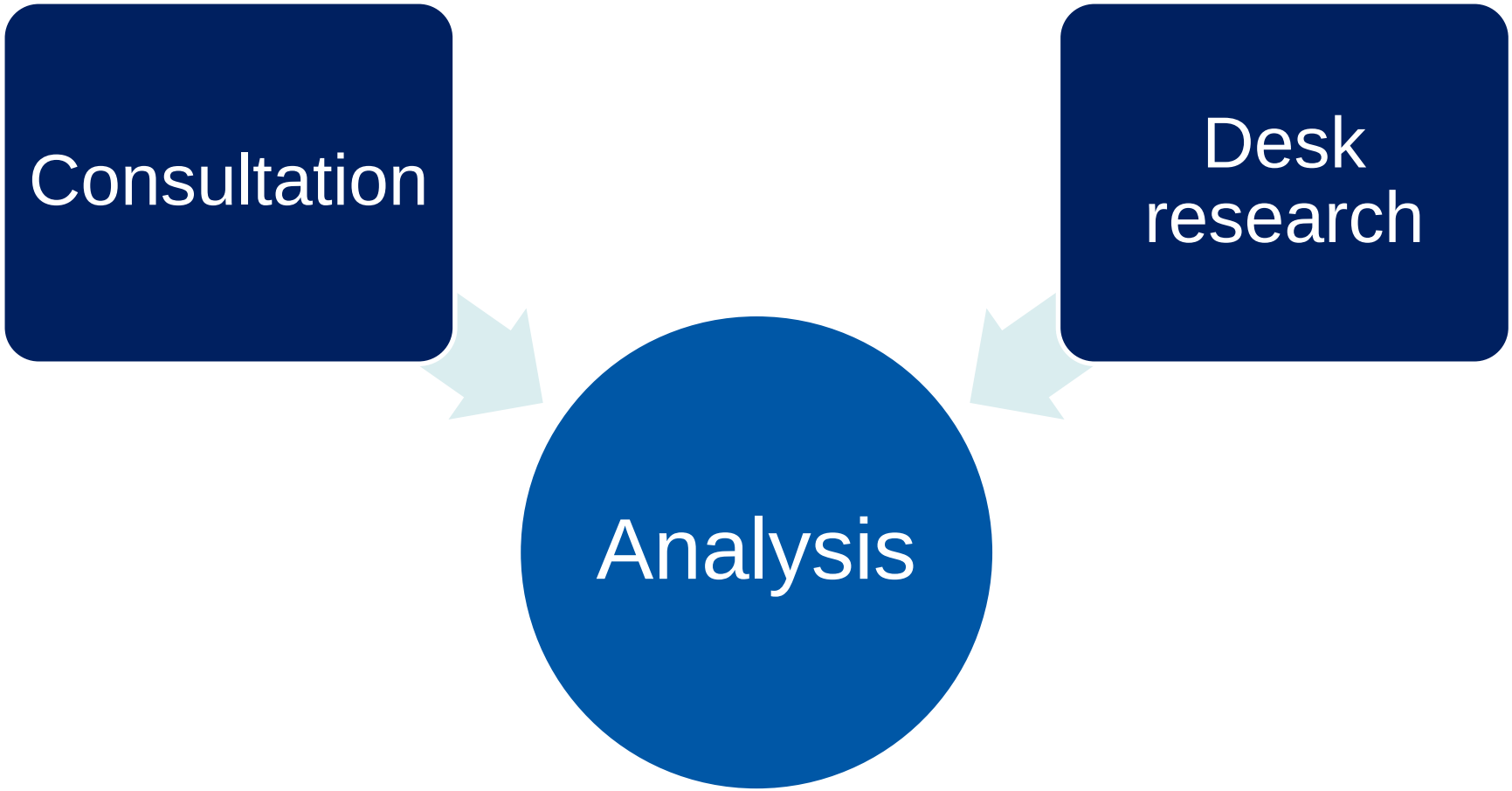
..Where do we stand?



Sources of information



Consultation strategy

When?

- October to June

Why?

- To complement desk research
- To collect perceptions and views on the Regulation

Who?

- Member States Competent Authorities and third countries
- Business Operators
- NGOs
- Scientific institutes, experts and laboratories
- Regulatory support businesses

Consultation strategy

When?

- 12 weeks, February –May 2019

Why?

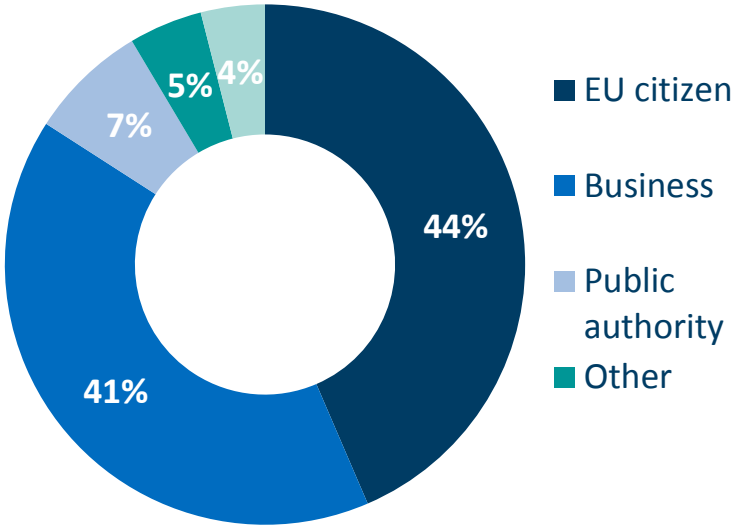
- To give citizens and experts the opportunity to provide their views on the Regulation

Who?

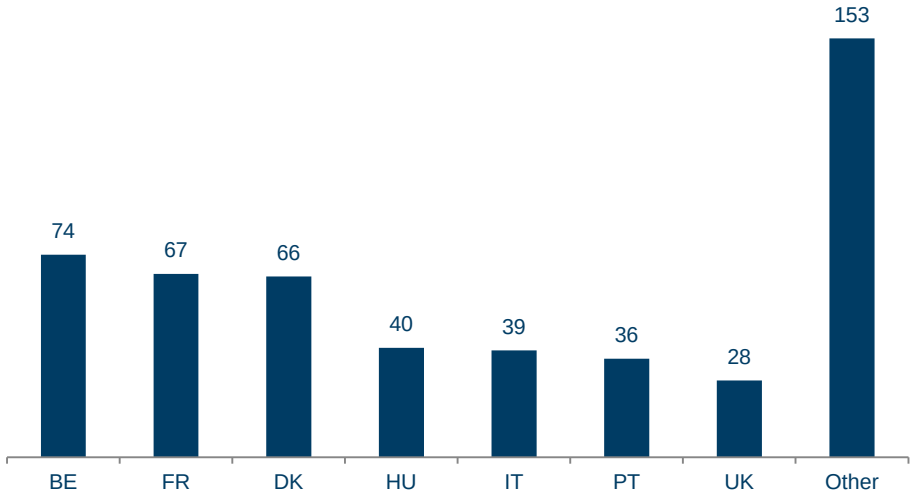
- 503 replies, among which 219 citizens
- Responses from more than 28 countries
- No campaigns identified

Background of respondents

Type



Country of residence



Consultation strategy

SME survey

Why?

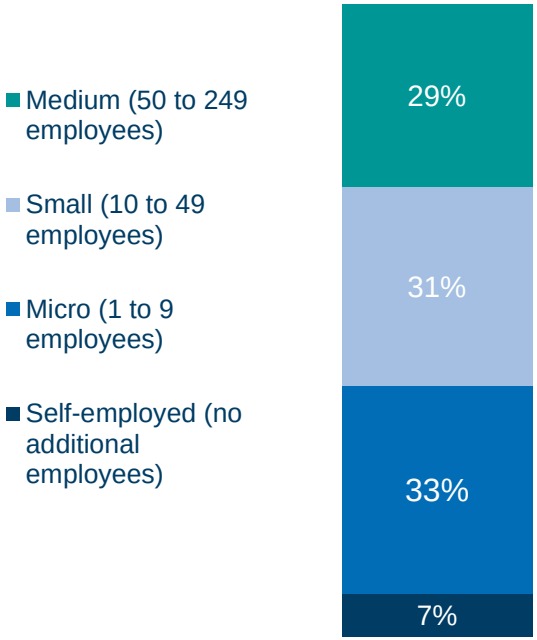
- To explore the needs and challenges faced by EU SMEs in the context of the FCM legislation

Who?

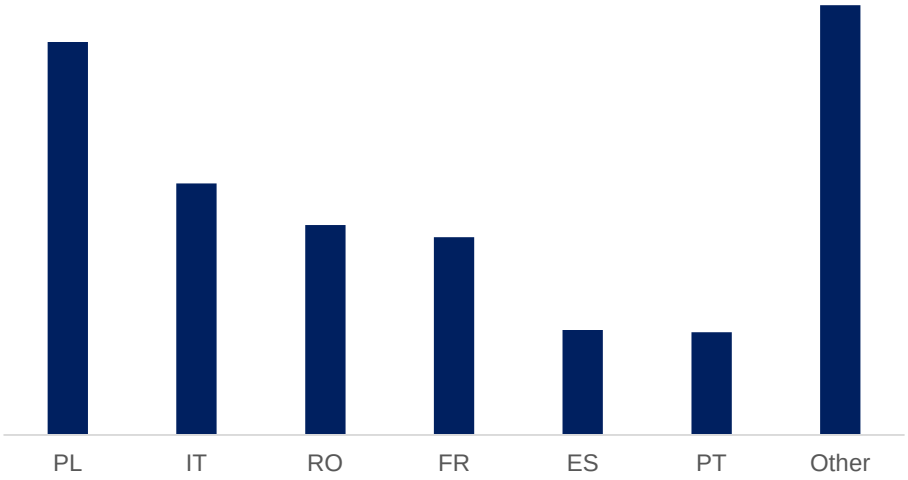
- 701 replies from 21 MS
- Distributed to the SME panel of the *Enterprise Europe Network* and managed by DG GROW

Background of respondents

Size



Country



Consultation strategy

Case Studies

Why?

- To gather first-hand data and facts on several aspects related to the FCM legislation
- To illustrate and exeplify complex issues

What?

- 6 case studies covering:
  - *The authorization process*
  - *Effects of the lack of harmonisation*
  - *Compliance along the supply chain*
  - *Challenges of SMEs*
  - *Enforcement and controls*
  - *Coherence of the FCM legislaiton*

Consultation strategy

Interviews

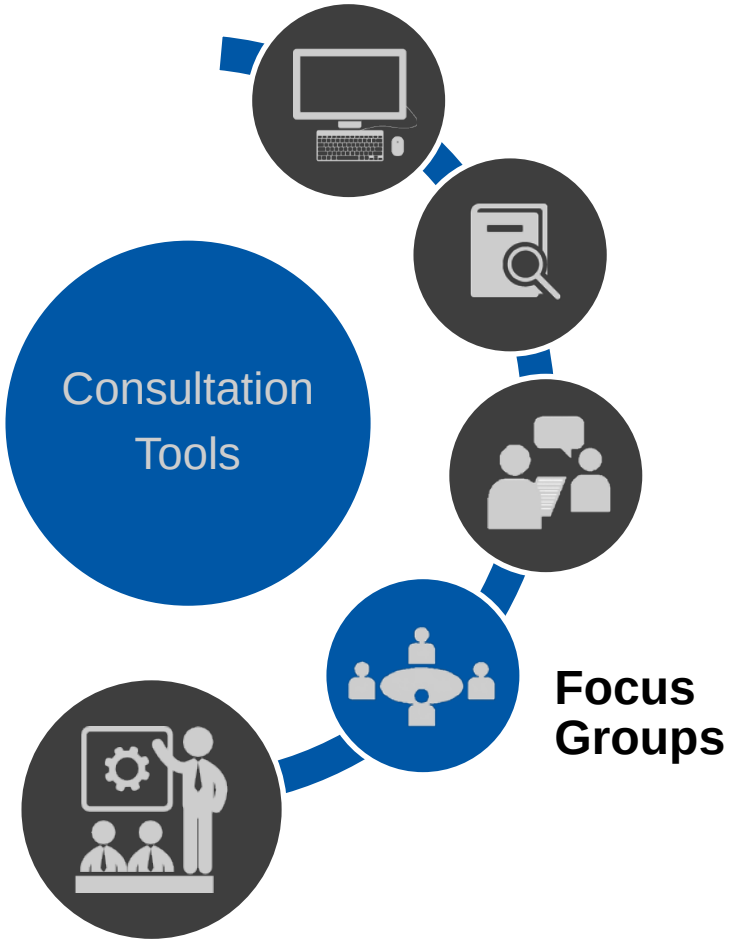
Why?

- To investigate, clarify and substantiate the evidence obtained via desk research and other consultation tools

Who?

- 40 interviews
- Relevant stakeholder groups:
  - *Member States Competent Authorities and third countries*
  - *Business Operators*
  - *NGOs*
  - *FCM experts and consultants*

Consultation strategy



Why?

- To stimulate discussion and gather information on several aspects related to the FCM legislation

What?

- 6 focus groups covering:
  - *Official controls*
  - *Effects of the lack of harmonisation*
  - *FCM and REACH*
  - *Risk assessment and management*
  - *Enforcement and controls*
  - *Coherence of the FCM legislation*

Consultation strategy

When?

- I WS: 24° September 2018
- II WS: 9° September 2019

Why?

- I WS: To present and validate the approach and methodology
- II WS: To collect feedback and further evidence

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SESSION 1 Effectiveness

Session 1 - Effectiveness

To what extent does the legislation meet the two major objectives on protection of health and functioning of the internal market?

EQ1: protection of human health

1. The **subject matter in Article 1 and definitions in Article 2** of the FCM Regulation are generally clear and encompassing and contribute to the objective of protecting human health. **Issue**:
   - ‘normal or foreseeable conditions of use’

2. The **positive authorised listing** approach offers an effective way of ensuring that the main substances used to manufacture FCMs do not pose a risk to human health. **Issues:**
   - Focus on starting substances
   - No harmonised approach for NIAS, which, by law, are to be evaluated by industry
   - No harmonised evaluation of colorants, PPA , solvents (Art 6 of Reg 10/2011)
   - Possible combined effects of migrants, multiple routes of exposure are sometimes considered as source of concerns

EQ1: protection of human health

3. The **FCM symbol (glass&fork)** is an effective vehicle of information, as the vast majority of consumers is aware of its meaning. **Issues:**
   - ❑ consumers need more instructions on the appropriate use of FCM
   - ❑ lower degree of understanding among consumers on AIMs

4. **GMP** play a crucial role in ensuring the safety of the final FCM. **Issues:**
   - ❑ lack of clarity and guidance as regards controls of GMP performed by Competent Authorities
   - ❑ application of GMP during the manufacturing of FCM imported from third countries

EQ1: protection of human health

5. There is uncertainty whether the system of **Official Controls** adequately enforces the requirements of the FCM legislation.
   Issues:
   - lack of resources and expertise at MS level
   - enforcement authorities develop different approaches in different MS: inspections, testing campaigns
   - lack of a registration system of business operators and lack of systematic data records of cases of non-compliance

EQ2: the internal market

1. The **purpose, subject matter, and definitions** of the Regulation (Articles 1 and 2) generally provide a good basis to the effective functioning of the internal market. **Issues:**
   - ❑ definition for the ‘deterioration in the organoleptic characteristics’ and ‘normal or foreseeable conditions of use'

2. The **EU positive list approach** for plastic FCMs contributes to the functioning of the internal market. **Issues**:
   - ❑ there are limited capacities to keep the positive lists up to date
   - ❑ while foreseen, there are no positive lists for active and intelligent materials and for recycled plastic materials yet.

EQ2: the internal market

3. From an industry perspective, overall **traceability** along the FCM supply chains is generally considered to be ensured and contributes to the effective functioning of the internal market.
   Issues:
   - ❑ SMEs face greater challenges in terms of awareness and ensuring traceability
   - ❑ the longer the supply chain, the greater the challenge to ensure traceability (outside the EU)

4. The **labelling** requirements of the Framework legislation further facilitate transparency in the supply chain. (minor) **Issue**:
   - ❑ clarity on whether a FCM manufacturer needs to mention a batch number or the production date on the material itself.

EQ2: the internal market

5. The **GMP** regulation provides a direction for ensuring quality practices in manufacturing without being prescriptive. **Issue**:

- NGOs and some of the interviewed business associations have expressed a preference for an integral FCM Regulation rather than having a GMP regulation separately
- the certification of businesses on compliance with GMP is costlier to SMEs as compared to larger companies
- challenges ensuring GMP implementation in third countries

EQ2: the internal market

6. **Declarations of compliance** are an important feature of the Framework Regulation that enhances transparency and trust. It provides users of materials with a detailed description of the materials' properties and thus increases certainty for companies. Issues:
   - ❑ DoCs and SD are mandatory for harmonised FCM
   - ❑ DoCs are requested by some MS for non-harmonised FCM
   - ❑ preparing several DoCs is particularly challenging for SMEs

EQ2: the internal market

7. As concerns **mutual recognition**, according to industry stakeholders national requirements lead to: (1) obstacles to trade and delayed market access; and (2) additional tests and the need to provide documentation in order to meet national requirements places an extra burden on businesses:
   - ❑ these effects are more pronounced with SMEs that do not have the resources to counter incorrect application of the mutual recognition principle
   - ❑ National rules and lack of mutual recognition is also a challenge for the use of complex and large machines that are in contact with food

Table discussions and reporting

- 1 rapporteur per table
- Rapporteurs complete the feedback document
- All feedback documents will be collected
- Reporting: maximum 3 minutes per table

+ *written contribution until 16 September*

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SESSION 1 Effectiveness

Session 2 - Efficiency

*What are the **benefits** and **costs** of the legislation and how can these be quantified / weighted?*

Disclaimer

- ***Quantitative data scarce***
  yet focus of evaluation questions

- ***Preliminary findings***
  need to be checked against some additional input

- ***Estimates and extrapolations***
  limitations and assumptions apply

- ***Focus on costs****,*
  instead of burdens

EQ 3: Benefits - Consumers

1. FCM legislation benefits health protection
    - Reduced exposure
    - Use of safer substances
    - Very high standard compared to other countries

Estimates suggest cost savings ranging in the EUR billions

Enforcement and controls: still room to improve, needed for realisation of full benefits…

EQ 3: Benefits - Industry

2. Harmonisation had beneficial effects
    - Openness of the internal EU market
    - More certainty for businesses
    - Avoidance of duplication of work
    - Arguably effects more pronounced in sectors where material-specific legislation exists

Harmonised risk assessment: cost savings ranging between EUR 10 to 25 million per year

EQ 3: Benefits – Competent Authorities

3. Cost savings linked to harmonised risk assessments are estimated to amount to about EUR 1 million per year

Legislation facilitates cooperation, knowledge exchange, ... but not feasible to quantify

EQ 4: Costs - Industry

1. Compliance costs for material producers estimated to amount to approx. EUR 50 million per year

Equivalent to approx. 0.03 to 0.5% of production value

Administrative costs linked to FCM legislation amount to 2 to 8% of total administrative costs

Costs for downstream users were not quantified

EQ 4: Costs – Competent Authorities

2. Total costs of about EUR 17.5 million to 26 million per year

About 70% of costs linked to for enforcement and controls

Some 160 to some 180 FTEs in EU, most of them on enforcement and controls

EQ 4: Costs – European Institutions

3. Total costs estimated to amount to about EUR 1 million per year (excl. JRC)

Of this, EFSA accounts for more than 50%

Budget at EFSA seemed to decrease over the last couple of years

EQ 5: Efficiency

1. Overall, there is clear indication that the FCM legislation has delivered on the objective to protect health of consumers
    - Benefits outweigh the costs of the legislation
    - Still room to improve (effectiveness)

2. Inconclusive evidence (due to data gaps) to assess efficiency with regards to functioning of the internal market

EQ 5: Efficiency

3. In general, harmonised approaches appear to be more efficient
    - Particularly for industry and for authorities
    - Avoid duplication of work
    - Sharing of burden and of knowledge

- Feasible for all materials?
    - Not same approach required for all materials
    - Opportunity to build on work already done
    - Framework Regulation provides good basis

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SESSION 2 Efficiency

Session 3 - Relevance & coherence

Have the scope and objectives of the Regulation been relevant to the needs of stakeholders, and do they remain so today?

Which parts are coherent and which parts are not coherent within the legislation itself and other relevant rules or practices?

EQ 6: Needs, interests and expectations of stakeholders

1. Regulation (EC) 1935/2004 reflects the needs of **consumers** for protection of human health and preservation of organoleptic properties of food.
   - ❑ The FCM legislation does not address protection of the **environment**, it is covered in other comparable pieces of legislation, such as REACH and the Waste Directive

EQ 6: Needs, interests and expectations of stakeholders

2. The plastics regulation reflects the needs of (large) **business operators**. The FCM legislation is more adequate for their needs than for those of medium-sized enterprises and of smaller ones.

3. **Member State** need more capacity and expertise to carry out inspections and controls (lack of access to analytical methods, need to train inspectors, organisation of tests with EURL).

EQ 7: Evolving science and innovation

1. Regulation (EC) 1935/2004 does not provide sufficient flexibility when it comes to considering **new scientific knowledge** and **technological developments**

2. There is **no mechanism in place to prioritise** the handling of certain substances of health concern

3. It is unclear to what extent Regulation (EC) 1935/2004 stimulated **research and innovation**

EQ 8: Internal coherence

1. The Framework Regulation and specific regulations co-act as intended. **Issues**:
   - ❑ The absence of EU harmonised specific measures for coatings, inks, adhesives, paper & board etc. represents a burden, to ensure that FCM comply with all relevant legal requirements (different in different Member States).
   - ❑ NGOs worry most about (i) cocktail effects of migrants & (ii) SVHC in FCM
     (subject to severe restrictions in FCM plastics regulation)

EQ 8: Internal coherence

2. Lack of harmonised rules for assessment of compliance/safety of final FCM

3. Delays in the publication of the Union lists of approved active and intelligent substances create a burden to companies, often SMEs on the EU market

4. The development of national provisions could challenge efforts to reach common rules for non-harmonised FCM

EQ 9: External coherence

1. Some stakeholders criticise the external coherence of the FCM legislation with **REACH**. However perceived inconsistencies are not always genuine incoherence.

2. Overall, FCM & REACH Regulations do not overlap but exchange of data between EFSA & ECHA should be improved

3. Insufficient rules for **dual-use** substances

4. The safety requirements of Reg.(EC) No 282/2008 on **recycled plastics** contradict the recycling targets in Directive (EU) 2018/851 on waste

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SESSION 3 Relevance & coherence

Session 4 - EU added value

What is the EU added value of Regulation (EC) No 1935/2004 in relation to its main objectives?

EU added value of Reg 1953/2004

1. Regulation (EC) 1935/2004 provides EU added value but its amount is reduced by incomplete implementation

EU added value of Reg 1953/2004

- Coherent framework in which measures can be taken at EU and national levels to cover all FCM

- The Regulation (EC) 1935/2004 provides a basis for securing a high level of protection of human health regarding individual materials, with benefits estimated to outweigh costs

- Main contributions:
  - The EU positive list approach
  - Declarations of compliance, traceability and labelling requirements

EU added value of Reg 1953/2004

The EU added value is weakened by gaps in implementation:

- Absence of specific measures for many substances
- Poor functioning of the mutual recognition system
- Gaps in the enforcement

EU added value – Reg 10/2011

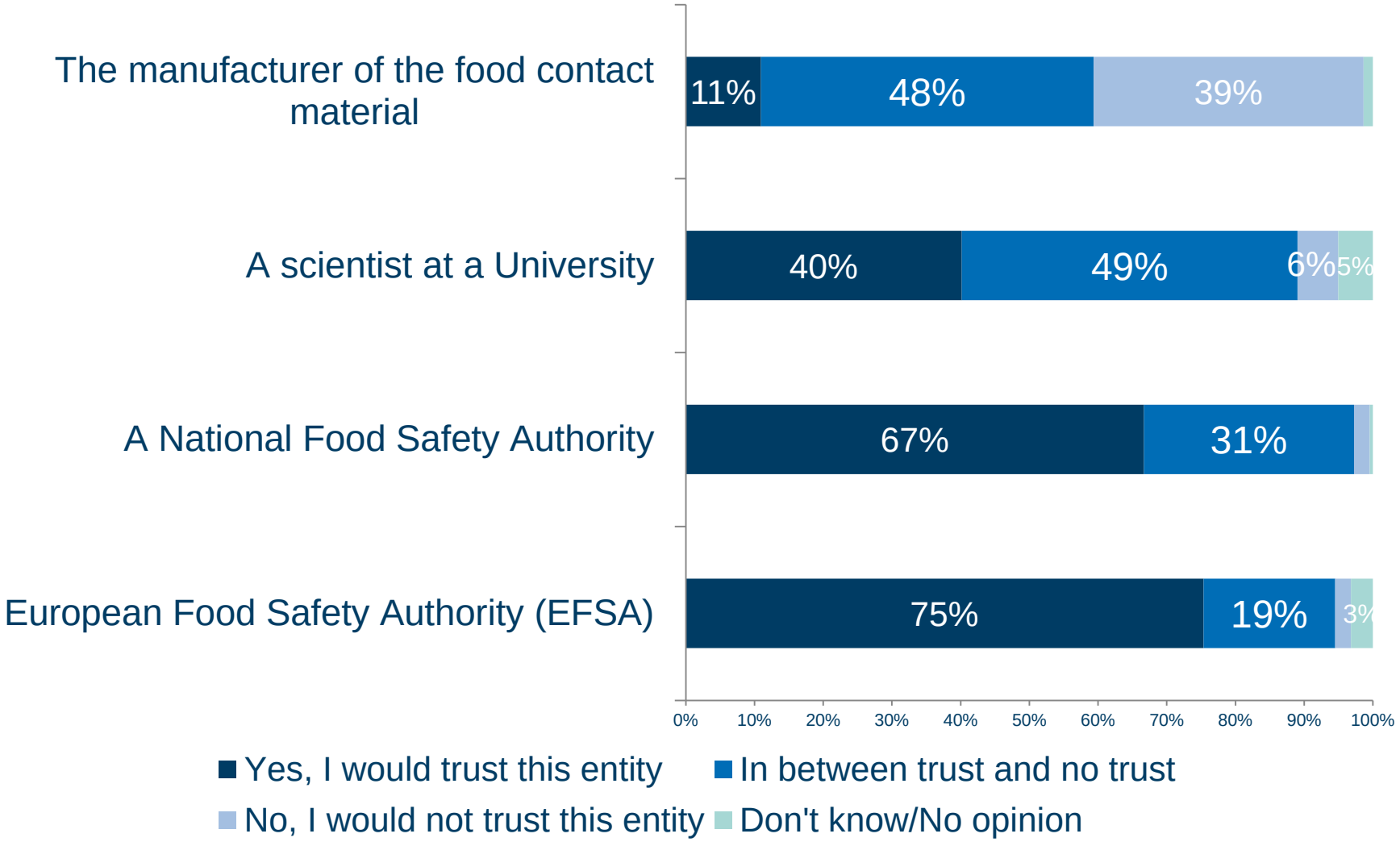
2) Regulation (EU) 10/2011 has brought considerable added value and has enhanced the regulatory framework for plastic materials
   - ❑ Collected evidence suggests that harmonised legislation is more efficient than following a non-harmonised approach.
   - ❑ This positive assessment contrasts with that of Regulation (EC) 450/2009, for which EU added value is considered to be low due to the absence of authorisation of active and intelligent materials

EU added value – stakeholders views

- There is a consensus among Member States, EU authorities, citizens and other stakeholder categories that EU intervention is of great added value
  - For **Member States**, harmonisation reduces the cost of implementing FCM legislation
  - For **NGOs**, harmonisation better protects consumers
  - For **businesses**, harmonisation positively contributes to the functioning of the internal market

  - *…What about **consumers**?*

How do you trust as a source of information on the safety of a chemical substance or a food contact material?



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SESSION 4
EU added value
+ concluding comments
on all EQs

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Concluding remarks

ECORYS

Until 16 September

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