Introduction to the study

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Introductory workshop to support the evaluation on the FCMs legislation

Monday 24th September 2018

Plan of the presentation

1) Introduction to the study
2) Overall approach
3) Consultation strategy
4) Tools

Introduction to the study

Objectives and scope

1) Objectives

- The overall purpose of this evaluation is to assess whether the current EU legislative framework for FCMs is fit for purpose and delivers as expected
- To provide the EC with quantitative and qualitative data and a comprehensive analysis

2) Scope

- **Effectiveness** of Regulation (EC) No 1935/2004 (Q1-2);
- **Efficiency** in relation to resources used (Q3-5);
- **Relevance** in relation to identified needs and problems (Q6-7);
- **Coherence** – internal and external (Q8-9);
- **EU added value** compared to what could have been achieved at Member State or international level (Q10).

About the study

From August 2018 to October 2019

- Data collection until April 2019
- Draft final report in August 2019
- Final report in October 2019
- Workshop to discuss results in September 2019

Ecorys + FCM experts

- **Ecorys - www.ecorys.eu**

Independent consulting (500 employees) - evaluation expertise
fcm@ecorys.com

- **FCM experts**

Alexandre Feigenbaum
Philippe Saillard

Evaluation questions - effectiveness

EQ1 - To what extent, has Regulation (EC) No 1935/2004 and subsequent implementation achieved its objective of providing the basis for securing a **high level of protection of human health and the interests of consumers** in relation to FCM?

EQ2 - To what extent has Regulation (EC) No 1935/2004 and subsequent implementation ensured the effective **functioning of the internal market** in relation to the placing on the market in the EU of FCMs?

Evaluation questions - efficiency

EQ3 - What are the **quantifiable benefits** of the FCM legislation, taking into account resources (cost, time, etc.) to stakeholders?

EQ4 - What are the **quantifiable burdens** of the FCM legislation, taking into account resources (cost, time, etc.) to stakeholders and are there aspects that could be simplified to improve efficiency?

EQ5 - Taking into account the answers to questions 3 and 4**, how efficient** is Regulation (EC) No 1935/2004 and its implementation tools in ensuring the safety of FCMs?

Evaluation questions - relevance

EQ6 - What are the **needs, interests and expectations** of the following stakeholder groups and to what extent does the current legislation address them?
a. Consumers and their representative organisations;
b. Business operators including food business operators and;
c. Member States' Competent Authorities?

EQ7 - To what extent has Regulation (EC) No 1935/2004 and its subsequent implementation allowed for **evolving science, prioritisation and innovation**?

Evaluation questions - coherence

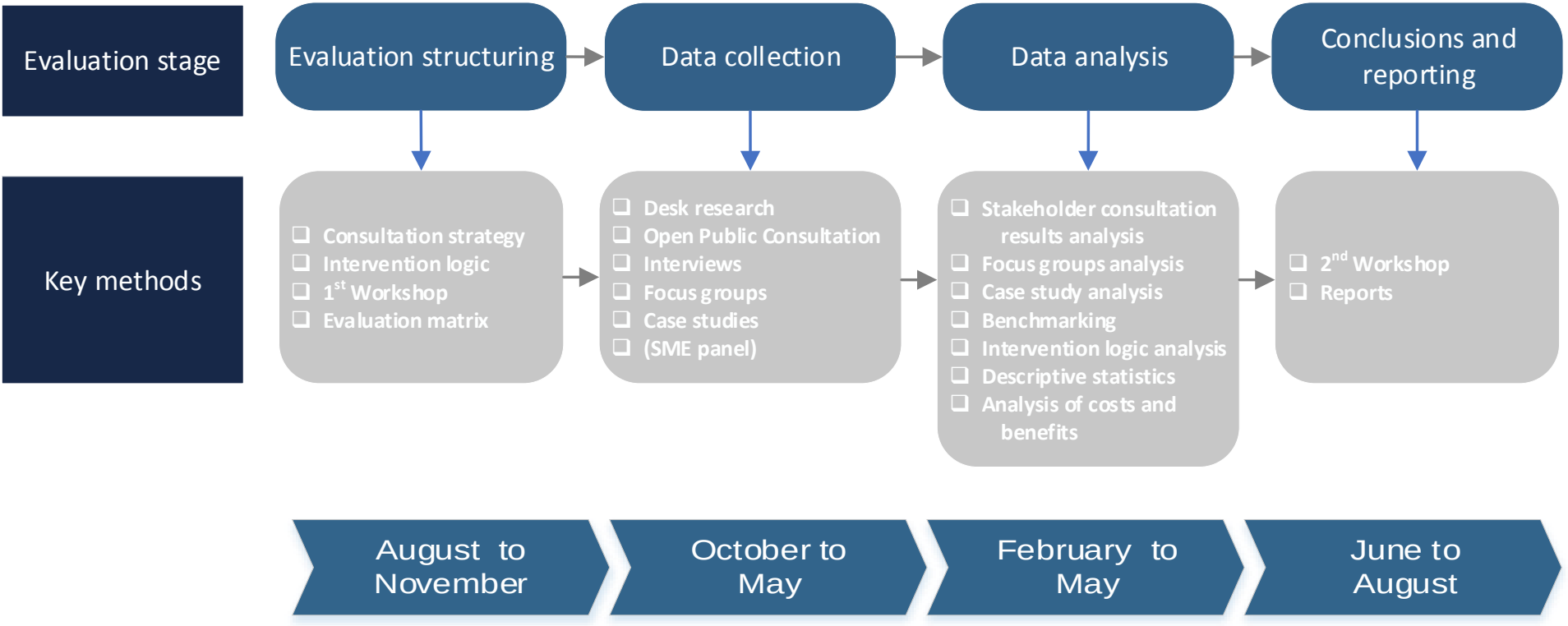
EQ8 - To what extent is Regulation (EC) No 1935/2004 **internally coherent**, including all of its implementing acts?

EQ9 - To what extent are Regulation (EC) No 1935/2004 and its subsequent implementation including the risk assessment and risk management approaches taken, **externally coherent** with other relevant legislation and policies?

Evaluation questions – EU added value

EQ10 - **What is the EU added value** of Regulation (EC) No 1935/2004 in relation to its main objectives?

Overall approach



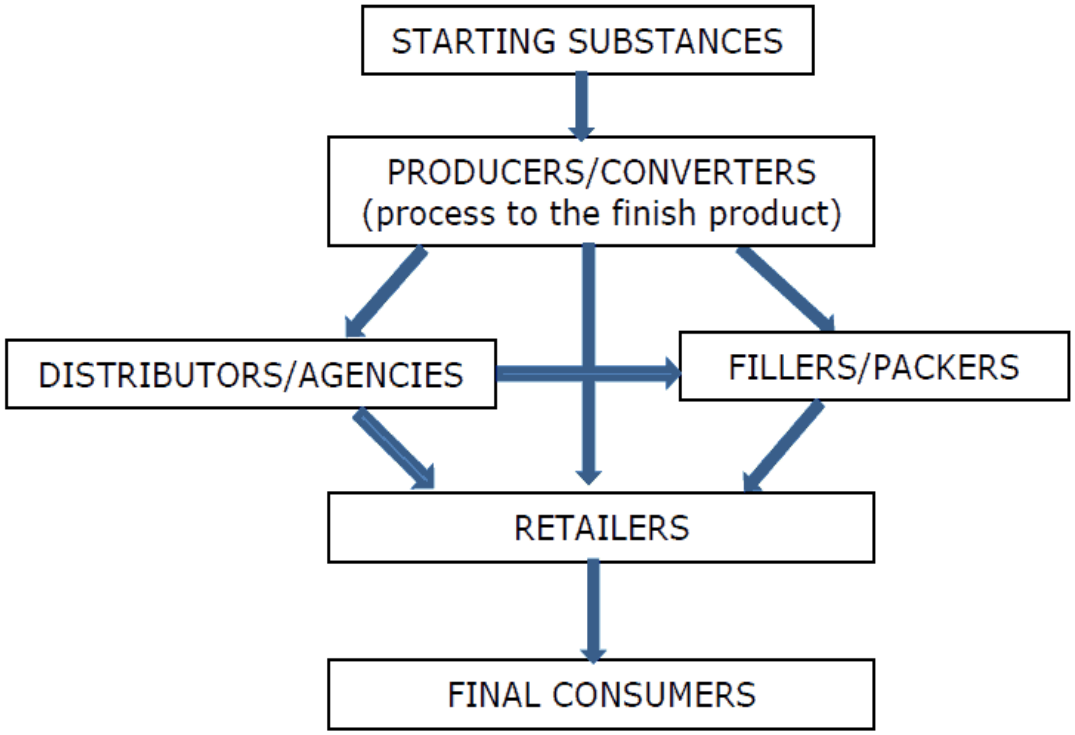
Consultation strategy

Objectives and scope

1) Objectives:

- **Complement the data and information** from the JRC baseline study, other studies and survey, reports, and other secondary sources
- **Collect perceptions and views of different stakeholder groups** on Regulation (EC) No 1935/2004

2) Scope: all evaluation questions



upstream

downstream

- Citizens
- NGOs
- Businesses (associations and companies)
- Member States

Source: JRC

- EU institutions (EC, EFSA, JRC)
- Supranational or international public bodies
- Scientific institutes / experts and laboratories
- Third countries

Tools

1) Interviews

2) Open Public Consultation + SME panel

3) Case studies

4) Focus groups

5) Workshops

Interviews – around 40

1) **Objectives:**
   - ❑ Identify key issues and sources of information
   - ❑ Gather in-depth information along the evaluation criteria

2) **Scope:** MS CAs (10+), NGOs (5+), professional associations (10+), EU bodies (5), international bodies and third countries (3+), scientific community (2)

3) **Timing:** until April 2019

Open public consultation

1) **Objectives:**
   - ❑ Gather (data and) opinion
   - ❑ Reach a wide range of groups

2) **Scope:** focus on consumers, but include also questions for experts in their professional capacity; all evaluation criteria, but focus on Relevance and consumer habits

3) **Timing:** beginning of 2019; 3 months

Case studies - overview

1) **Objective:** Illustrate specific elements and/or effects of the regulations

2) **Scope:** Six topics
   - ❑ Authorisation procedures
   - ❑ Differences in guidance documents between EU and national level
   - ❑ Compliance along the supply chain
   - ❑ Import vs EU manufacturing
   - ❑ SME effects
   - ❑ Citizen habits

3) **Timing:** until April

Case studies - focus

Case name	Description
Theme 1: Application to Market (authorisation procedures)	Focus on timeline/sequence, general degree of complexity the processes, costs, and benefits.
Theme 2: EU vs National	Focus on contrasting harmonized vs non-harmonized frameworks, e.g. on risk assessment.
Theme 3: Compliance	Focus on compliance requirements, costs, and benefits.
Theme 4 : Small and Micro businesses	Focus on challenges particular to smallest segments.
Theme 5: Import vs domestic manufacture	Focus on implications for EU imports and domestic production.
Theme 6: Consumer habits	Focus on consumer awareness, risks and perceptions.

Case studies – authorisation procedures

1) **Aim of the case study** - to assess efficiency (cost and benefits) of the whole process, from risk assessment to authorisation

2) **Specific cases:**
   - ❑ At the EU level e.g. for substances used in plastic FCM
   - ❑ At the national level for the same substance in other FCM
   - ❑ At the national level for a substance(s) used in FCM for which no authorisation has been considered at EU level

Case studies – example of activities

1) **Desk research**
2) **Timelines tracking (authorisation procedures)**, e.g. CA and EFSA, risk management
3) **Supply chain analysis**
4) **Questionnaire to companies**
5) **Interviews with associations and NGOs**
6) **Analysis of costs and benefits**

Focus groups

1) Objective:

- ❑ Explain and verify findings from other tools

2) Scope: Possible topics

- ❑ Authorisation procedures (risk assessment and risk management)
- ❑ Guidance documents (EU and national level)
- ❑ Compliance along the supply chain
- ❑ Import vs EU manufacturing
- ❑ SME effects
- ❑ Consumer habits

3) Timing: February - April

Workshops

1) **First workshop** – validation of the methodology

2) **Second workshop** – feedback on the conclusions, probably in September 2019

Questions and feedback on the approach and the methodology

Plenary discussion

Stakeholder perceptions on the performance of the legislation

Effectiveness

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

- What are both the main positive and negative aspects of the legislation at each level of the implementation chain?

Efficiency

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

Relevance

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

Coherence

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

EU Added Value

Has it been better to have the legislation at EU level or alternatively at national level?

Next steps

Please contact us at
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