Summary of the DG SANTE introductory workshop to support the evaluation on Food Contact Materials (FCM) legislation

Monday 24th September 2018
Room 0D, Centre Borschette, Rue Froissart 36, 1040 Brussels

Welcome and introduction

The Commission (Bruno Gautrais, DG SANTE E2) welcomed the participants and presented the agenda of the workshop. The great variety of stakeholders attending the meeting has been acknowledged by Sabine Juelicher (Director E Food and Feed Safety, Innovation; DG SANTE), who described the workshop as a structured opportunity to gather views from all the important actors involved in the field of FCM.

The Commission outlined the size and diversity of the FCM sector, estimated at around 100 billion EUR per annum in Europe, covering food packaging, equipment, machines, containers for storage and transport with many businesses involved including manufacturers, designers, importers, distributers, retailers and finally consumers.

The Commission emphasized the two objectives of the current FCM Regulation, namely protecting human health and ensuring the functioning of the internal market. The Commission stated that in order to achieve these objectives it is of paramount importance that rules are clear, consistent and proportionate. The importance of innovation and development, the necessity to facilitate transport and storage of food and the role played by SMEs were highlighted.

The Commission stated that views and ideas collected throughout the workshop will represent valuable inputs to support the structuring phase of the evaluation. The Commission also reminded participants that the objective of the study is only to assess how the Regulation is currently working, and not to give suggestions about future legislation. Only after the evaluation the Commission will consider whether actions will need to be undertaken.

The need for factual and reproducible data was stressed, underlining that an evidence-based analysis of the functioning of the legislation will allow for better results of the evaluation.

Part 1: Overview and background

The Commission provided an overview of the state of play of the FCM legislation.

The first presentation set out the background of the legislation and described the history of the evolution of the FCM legislation, with some relevant milestones. Some key topics were mentioned, such as the use of positive authorised lists of substances, particularly for plastic FCMs, the approach towards the risk assessment, the information flow along supply chain, the enforcement of the Regulation across MS and its possible overlaps with other EU legislation.

Since its inception in 1976, FCM legislation at EU level has never been evaluated whilst several issues have been raised on the current approach, including lack of specific harmonised legislation for materials other than plastics and coherence with other chemicals legislation. .

Some insights on the evaluation process according to the Better Regulation were provided. The role of stakeholders has been stressed as crucial for the policy making process. The Evaluate-first principle has been also recalled. The Commission briefly illustrated the policy cycle. In this study, the Contractor is asked to perform a retrospective type of evaluation and assess what is really working as intended, what is not and why.

The Commission also described the timeframe for the evaluation consisting of a Roadmap, the study itself (with all the related consultation activities), the publication and dissemination of the report and finally a staff-working document drafted by the EC expected in early 2020.

Comments on the Roadmap[1] already indicate some general concerns regarding the Regulation, including the need for more harmonisation, improved information flow, the need to take into account scientific developments and a shift of emphasis on the final article. Stakeholders also consider that there should be better coordination with other chemical legislations (REACH) and EU policies (circular economy) and that participation of stakeholders, including civil society must be ensured throughout the evaluation process.

Other EC initiatives have been mentioned, which partially overlap with the evaluation exercise and will be taken into account (e.g. fitness check on food law, evaluation of REACH, strategy on plastics under the circular economy etc.), as well as other EU initiatives (EP Implementation Assessment Study on FCM Regulation (EC) No 1935/2004, position papers from stakeholders).

The Commission invited stakeholders to find more information on the Evaluation webpage[2] .

The second presentation focused on the findings of the JRC report on non-harmonised sectors.
Data collection covered the following areas:

- Market/sectorial data
- Regulatory framework
- Risk assessment approach in MS (comparison of national measures)
- Enforcement and official controls in MS (audits, BTSF, RASFF etc.)
- Cost and burdens, barriers to trade

Results from the data analysis will contribute to the evaluation, shedding light in the areas of effectiveness and efficiency and providing valuable data to assess burdens and trade related issues in the non-harmonised sectors.

[1] https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429_en
[2] https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/evaluation_en

As for effectiveness, differences in national approaches towards the risk assessment and a general lack of clear requirements could potentially hamper the safety of FCM. As regards efficiency, an extra burden has been identified with respect to lack of standards and methods, multiple and diverging legislation, issues with mutual recognition.

The third presentation focused on the risk assessment and the role of EFSA in this regard. Specific issues such as non-intentionally added substances (NIAS) were addressed as well as coherence with other legislation such as that on biocides and cooperation and synergies with work of Member States and other EU agencies such as ECHA.

Part 2: Perspectives from stakeholders on the functioning of the legislation

Different stakeholders (NGOs and industry representatives) presented different aspects of the FCM Regulation.

NGOs (CHEM Trust; HEAL; Client Earth and BEUC) gave a joint presentation, pointing out deficiencies in the current system for regulating chemicals in FCM. They described the system as slow, outdated and not in line with growing consumers concerns about chemical substances. Reference was made to Eurobarometer data indicating that a vast majority of consumers are concerned about chemicals and do not feel well informed about potential dangers. The environmental dimension has been mentioned as well, in particular plastics recycling.

The lack of harmonisation has been pointed out as an outstanding issue. Moreover, it was stressed that the system should be reviewed more often, e.g. REACH is reviewed every 5 years.

Other aspects of the Regulation that should be improved include:

- Specific harmonised measures for all FCMs;
- Integration of REACH information on chemicals;
- Grouping of substances;
- Possibility to include the principle of Cut-off criteria;
- Improved transparency;
- Assessing of mixture of chemicals;
- Assessment of NIAS (Not intentionally added substances);
- No tolerance approach for endocrine disrupting chemicals (EDC);
- Coherence with the circular economy initiative;
- Innovation in terms of safer materials /services, not only in substances;
- Link with the 7th Environmental Action Programme;
- Balanced representation of stakeholders in the expert group on FCM.

Professional associations presented the perspectives of the FCM manufacturing industries (Plastics Coordination Group and Plastics Europe, and Cross Sector Group and Flexible Packaging Europe), representing both the harmonised and non-harmonised sector.

Plastic manufacturers acknowledged what has been achieved through the harmonised approach, in particular with regard to the positive authorised list approach, the clear requirements for the Document of Compliance and guidance documents available. The utility of the FACET exposure tool developed by JRC was also acknowledged.

As well as the benefits brought by the harmonised approach, the plastics industry also pointed out some weaknesses of the system, in terms of:

- Analytical methods and tests not always clearly defined (technical guidelines on migration testing have not yet been published). A discrepancy between requirements to be checked and technical limitation to measurements has been raised;
- Existence of MS measures, allowed by the subsidiarity principle;
- Very limited access to *in silico* tools;
- Lack of pre-submission discussions with EFSA panel, which would ensure a smoother process and, possibly, the early detection of issues; the general lack of exchange with the Panel is mainly due to lack of trust from both sides;
- Insufficient opportunities for direct consultation and exchanges on (diverging) scientific opinions;
- High barrier for new products development hampering innovation;
- Lengthy risk assessment and authorisation process.

The views of the non-harmonised sectors have been shared as well (Cross Sector Group). Article 3 of the Regulation has been reported as the cornerstone for ensuring compliance, being universally accepted and applicable to all FCM. However, the lack of harmonised, official guidelines on how to ensure compliance has been pointed out.

The main issues in the field of non-harmonised FCM, include:

- Multiple legislation to comply with, thus requiring a great deal of expertise and possibly posing problems to SMEs;
- Language barriers in national rules;
- Different interpretations and expectations of enforcement authorities;
- Creation of barriers to trade;
- Lack of clear requirements for non-EU producers willing to import in EU;
- Lack of EU wide accepted test methods for non-plastics;
- Lack of official rules on how to demonstrate compliance with Art. 3 by industry

The last presentation shed light on enforcement of the FCM Regulation across EU Member States (KLZH Switzerland). The identified main elements of enforcement included: inspections to businesses, controls on products at retail level, and finally documentation controls, mainly on DoC and supporting documents. The

enforcement system has been depicted by the presenter as highly inefficient and full of holes.

During the presentation, five main enforcement issues were raised:

- The lack of an European-level working group on enforcement;
- The excessively high number of substances, practically impossible to check (approximately 100.000 different chemicals are expected to be present in all different types of FCMs, of which only around 10.000 are intentionally added, about 1000 are specifically regulated, and less than 100 are effectively controlled by enforcement);
- Lack of resources for FCM controls (and lack of competence at local enforcement level);
- Lack of knowledge on risk associated with migration from FCM (substances with unknown toxicity and migration behaviour);
- Lack of adequate sanctions (e.g. fines).

Positive examples in the field of enforcement were mentioned as well, among which a Member State that has developed a register for FCM businesses on inspections as well as a pilot project on GMP enforcement, that aims at collecting data from business operators.

At the end of the presentations, the Commission opened the floor for discussion.

With regard to enforcement, an NGO inquired about possible strategies to improve enforcement. Fines have been proposed as an effective tool.

A professional association acknowledged what has been already achieved in terms of safety of FCM put on the market. It recalled that more effort should be put in communicating such positive results, suggesting that more attention in producing compliant FCM is preferable to applying fines at a later stage.

A laboratory testing facility raised the issue of trade with non-EU countries, requiring a simple, fast and transparent approachable to adapt to the fast-changing world. For instance, India and China are developing positive lists that are in contrast with EU lists, showing the urge to act accordingly. The Commission replied that the international dimension is also taken into consideration, and that third countries have been invited to the workshop for this purpose. EFSA underlined that there is constant dialogue with third countries, the latter sometimes interested in using EU approach.

Another professional association recalled the importance of a fact-based evaluation and inquired about the statement on the effectiveness of Art 3 in protecting human health, asking for the evidence behind such statement.

Another stakeholder stressed the role of food industry in performing controls, narrowing the gap between FCM industry and consumers. The same stakeholder underlined that the approach towards assessment of NIAS should differ from IAS;

NIAS are subjected to a range of conditions, i.e. impurity level, which would make the usual approach scientifically incorrect.

Finally, an NGO recalled the gap between the enforcement of REACH and the enforcement of FCM.

Part 3: The evaluation process

The Contractor (Ecorys) introduced the evaluation team and recalled the importance of the workshop in supporting the study with views regarding the performance of the legislation. The active participation of stakeholders has been encouraged.

The planning was presented in detail to the participants. The study started in August 2018 and will last slightly more than one year, with the final report due in October 2019.

The Contractor recalled the objective of the study - looking backwards and assessing whether the current legislation is fit to purpose and is delivering as expected. The five classic evaluation criteria will be covered, namely:

- Effectiveness (in achieving the objectives of the Regulation)
- Efficiency (in terms of resources used)
- Relevance (in relation to identified needs of stakeholders)
- Coherence (internal as well as external)
- EU added value

The five criteria are further articulated in 10 evaluation questions (EQs); replies will be strictly evidence-based and built on facts and actual findings.

The Contractor clarified that the overall approach will build on the Better Regulation guidelines, and will include four main stages: structuring, data collection, data analysis and reporting. The Contractor informed that the research team is currently involved in the structuring phase, collecting information to answer the EQs and will design all consultation activities, including the related questionnaires.

The **Consultation strategy,** running from October to July has the twofold objective to complement data and information available (e.g. through documents, reports and position papers) as well as to collect perceptions and views from stakeholders. The Contractor will especially welcome insights on the quantification of benefits.

All relevant stakeholders will be involved in this process, including:

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

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

The Contractor listed the tools that will be used during the study, in particular during the data collection phase. Among them:

- **Interviews**: they will contribute to identify key issues and gain in-depth information. Around 40 interviews will be performed, among which 10+ with MSCAs, 5+ with NGOs, 10+ with professional organizations, 5 with EU bodies, 3+ with international bodies and third countries and 2 with the scientific community
- **OPC:** the questionnaire will be uploaded on EU survey for 12 weeks. It aims at collecting consumers' views, the outcomes will mainly fit into the Relevance EQs
- **SME panel:** through the Enterprise Europe Network
- **Case studies**: they will illustrate specific elements or effects of the Regulation. Six topics will be covered:
    - Authorisation procedures
    - Differences in guidance documents between EU and national level
    - Compliance along the supply chain
    - Import vs EU manufacturing
    - SME effects
    - Citizen habits
- **Focus groups:** they will be used to validate information received by other consultation tools and the case studies
- **Workshops:** one during the structuring phase (ongoing) and a second one at the end of the study, to present the main findings to stakeholders

Main suggestions made by stakeholders on the evaluation study approach include:

- Increase dialogue with ECHA or REACH Competent Authorities
- Carefully look at real health risk associated with FCM, rather than perceived risk
- Ensure a balanced representation of interests in the consultation strategy (NGOs vs Industry)
- Take into consideration not only the food packaging sector, but also the kitchenware and manufacture plants
- Take into consideration enforcement

One NGO underlined the importance of including ECHA and/or national Competent Authorities active under the REACH legislation.

Industry representatives suggested to, when looking at effectiveness, carefully look at real cases in which the Regulation has not been effective in protecting human health stressing that attention should be on real, rather than on

perceived risk. An NGO mentioned several studies that differentiate between false alarms and real health risk. With regard to the risk posed to human health by FCM, the lack of epidemiological studies on FCM has been mentioned.

NGOs pointed out that the methodological approach should ensure a balanced representation between industry and NGOs. The contractor explained that the results of the consultation process would be presented per stakeholder group.

It has also been stressed by the industry to carefully consider not only the packaging sector, but also the kitchenware manufacture and manufacture plants in which foodstuff is processed. Those items are fully covered by the Regulation, but difficult to be handled due to the high variety of materials and pieces of legislation applied. They suggested assessing the burden in these specific cases.

A third country underlined that the strategy focuses a lot on what has been done, but does not assess the gap between reality and requirements. The Contractor recalled that the overall strategy needs to follow the BR guidelines.

Plenary discussion:

The Contractor asked for the active participation and the sharing of evidence supporting the statements. The plenary discussion followed the five evaluation criteria, allowing stakeholders to share their views for each criterion.

EFFECTIVENESS

Industry questioned the effectiveness of the Regulation as regards the second objective of the Regulation (*ensuring the effective functioning of the internal market*). For instance, having national measures results in a variety of approaches, possibly hampering this objective. More harmonisation at EU level would be beneficial for this purpose.

A Member State acknowledged that harmonisation of certain sectors had a positive impact on the safety of FCM. On the other hand, many issues arise in the not harmonised ones and an EU-level approach would be desirable. In fact, discrepancies among national measures will affect the functioning of the internal market.

Another MS raised the issue of a correct information flow along the supply chain, which is built on trust. For instance, the failure of a single link in the supply chain will result in the whole system failing. This trust-based system is highly fragile, so there is a need to raise awareness among business operators on how to ensure compliance. A joint effort of industry and MSCA would ensure the correct functioning of the system.

EFSA underlined that many significant materials are not yet covered by specific measures; for instance, very stringent requirements are applied to recycled plastics, but not on other recycled materials. Industry and NGOs shared this concern about lack of harmonisation. Moreover, it has been pointed out that the concept of positive lists is disconnected from the actual use of such substances.

Taking into consideration the use would imply more complex evaluation criteria, and a shift from hazard to risk.

A business operator acknowledged that the risk assessment process is based on scientific findings and that the complexity of the subject requires a sophisticated approach, albeit burdensome. On this topic, another industry representative replied that the legal framework should be modernized to stay up-to-date and that the risk assessment is not entirely based on science; in fact, the lack of completion could allow for misinterpretation of the concept of risk.

A participant also suggested that supranational recommendations and guidance would help in achieving more harmonisation among Member States.

EFFICIENCY

On the quantification of burden, an industry association claimed that duplication of work, due to lack of trust in the industry sector, creates a considerable burden on business operators, although not easy to quantify. Another industry association mentioned the excessive burden on business operators associated to very costly migration tests, questioning the utility of such tests in protecting the human health.

A Member State informed the Contractor that costs related to enforcement could be quantified. In fact, data on enforcement (e.g. number of samples inspected) could serve as a proxy to evaluate the burden on Member States' Competent Authorities. On this matter, the Contractor replied that enforcement costs would be carefully assessed.

Costs on public health are acknowledged as very difficult to assess by several stakeholders. Studies aiming at translating, in monetary value, the cost of exposure to certain chemicals have been mentioned by NGOs, but the uncertainty associated with such studies was also recognised. EDC and associated healthcare costs have been suggested as a possible proxy to estimate health costs.

With regard to the quantification of benefits stemming from the Regulation, a consumer organization suggested a study performed by EC on cumulative benefits of EU chemicals legislation. On the other hand, an industry association suggested estimating the benefits considering the costs that would be encountered if the Regulation would not be in place, e.g. the reduction of shelf life and consequent food losses.

Finally, the benefits of the Regulation in triggering innovation were highlighted by an NGO.

RELEVANCE

Consumer organizations claimed that consumers' needs are not sufficiently addressed in the framework Regulation. An industry operator agreed, underlining that more clarity on innovation could benefit consumers. It was recalled that the Regulation is clear in terms of objectives, but not clear in terms

of how to achieve them. More clarity in the procedures, *e.g.* in terms of guidance documents, would be welcomed by business operators.

A Member State recalled the importance of hygienic aspects, which are handled in Reg. 852/2004 on the hygiene of foodstuffs, but not FCM.

EFSA stressed the need to take actions towards circular economy, and reminded that recycling and reuse of materials will be encouraged in the future.

COHERENCE

A Member State emphasised the need for coherence with REACH and other relevant food legislation. On this note, a business operator underlined that the positive list for plastic substances still contains many chemicals that are claimed to be of high concern under REACH. The positive lists should be kept updated and coherent with the REACH Regulation. The industry also suggested creating and/or implementing existing databases, which could serve as a useful tool to cross-check information and avoiding inconsistencies.

An NGO proposed to adopt hazard based cut-off criteria, which is already applied in the pesticides legislation.

A representative of the industry highlighted inconsistencies in the scope of biocides, the latter being used in FCM as well as in other applications.

EU ADDED VALUE

Industry representatives acknowledged the EU added value of the Framework Regulation, stating that it is well recognized worldwide and used as an inspiration in third countries. Tools such as guidance documents on DoC and on technical terminology have been recognized as highly useful.

A Member State reported that the Regulation brought numerous improvements in the field of FCM, but joint effort from all interested parties would further fine-tune the results.

Conclusions

The Contractor clarified the next steps, inviting the stakeholders to provide any material which can be relevant for the study (e.g. reports, examples, databases, statistics etc.). The Commission thanked the participants for their fruitful contributions and recalled the importance to engage in the consultation activities that will be implemented during the study.