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European Commission

INCEPTION IMPACT ASSESSMENT

Inception Impact Assessments aim to inform citizens and stakeholders about the Commission's plans in order to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options.

TITLE OF THE INITIATIVE	Revision of EU rules on food contact materials (FCMs)
LEAD DG (RESPONSIBLE UNIT)	DG SANTE E2
LIKELY TYPE OF INITIATIVE	To be determined
INDICATIVE PLANNING	Q4 2022
ADDITIONAL INFORMATION	Evaluation of food contact materials (FCM) legislation

The Inception Impact Assessment is provided for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the Inception impact assessment, including its timing, are subject to change.

A. Context, Problem definition and Subsidiarity Check

Context

Food contact materials ('FCMs') include food packaging, everyday household items such as kitchen- and table-ware as well as machinery and surfaces used in food manufacturing, preparation, storage, transport and distribution. Whilst they are vital to the integrity and safety of the food supply chain, chemical substances can migrate from FCMs into food and thus contribute to consumers' exposure to those substances. Therefore in order to protect consumers, Regulation (EC) No 1935/2004 sets basic EU rules for all FCMs, which aims to secure a high level of protection of human health, protect the interests of consumers and ensure that the internal market functions effectively.

The Regulation requires FCMs to be manufactured so that chemical substances do not migrate into food that would endanger human health and sets other rules such as those on labelling and traceability. It also allows specific rules to be introduced for particular materials and establishes a process for the risk assessment of substances by the European Food Safety Authority (EFSA) and eventual authorisation by the Commission. This has been achieved primarily for plastic FCMs, whereby compositional requirements and a list of authorised substances together with certain restrictions such as migration limits, have been established. For many other materials, such as paper and cardboard, metal and glass materials, adhesives, coatings, silicones and rubber, specific rules do not exist at EU level and national legislation may apply.

The basic provisions of the present EU legislation were introduced in 1976 but until recently had never been evaluated. Experience with implementing the legislation, feedback from stakeholders and evidence being collected through the ongoing Evaluation of FCM legislation indicate problems that are linked to the absence of specific EU rules, which leads to uncertainty about safety of some FCMs and internal market problems. Further specific EU legislation is supported by all stakeholders including EU Member States, the European Parliament, industry and non-Governmental organisations. However, there are also currently several fundamental issues present in the existing approach to regulating plastic FCMs at EU level.

Legislation on FCMs is directly relevant for the success of key Commission policies under the EU Green Deal. In particular, the Farm to Fork Strategy commits to revise the FCM legislation in order to improve food safety and public health (in particular in reducing the use of hazardous chemicals); support the use of innovative and sustainable packaging solutions using environmentally-friendly, re-usable and recyclable materials, and contribute to food waste reduction. A new initiative is therefore also critical to support the Circular Economy Action Plan (CEAP) including a follow-up to the 2018 Plastics Strategy, to ensure packaging is re-usable and recyclable. It is also necessary to contribute to the ambitions of the Chemicals Strategy for Sustainability towards a toxic free environment, in particular concerning action related to the most hazardous chemicals as well as taking into account their cumulative and combinative effects.

The COVID-19 pandemic has also highlighted the importance of FCMs in safeguarding food supply chains and ensuring EU food security in times of crisis.

Problem the initiative aims to tackle

The EU Green Deal thus calls for addressing the **fundamental issues** being identified in the ongoing Evaluation

of FCM legislation, which are relevant to both main objectives of the current legislation concerning **the protection of human health** and **the functioning of the internal market**. The fundamental issues relate both to the absence of EU specific measures (1) as well as various aspects of the current EU rules (2 – 8) as follows:

1. Lack of functioning of the internal market and possible safety issues for non-plastics FCMs

The absence of specific EU rules for most sectors other than plastics has resulted in a lack of a defined level of safety and consequently no appropriate legal basis for industry to carry out compliance work. Although specific rules exist at national level for certain materials, they often differ significantly between Member States or are outdated, creating unequal health protection for EU citizens and unnecessary burden for businesses, such as multiple testing regimes. In other Member States, national rules are absent where they do not have sufficient resources to act on their own. No standards exist at international level (e.g. Codex Alimentarius) and self-regulation via industry guidance has reached neither the necessary level of implementation nor agreement by all actors on appropriate standards. These problems have persisted in the absence of EU intervention and according to stakeholders also cause problems for the functioning of the EU market. The scale of the issue is also linked to the significant size of the European industry, which is circa. €100 billion per annum, approximately two-thirds of which involves the production and use of non-plastic materials, including many small and medium sized businesses (SMEs). Absence of specific EU rules and subsequent multiple laws in different Member States also complicates control of imports, which contribute a significant proportion of products on the EU market, especially kitchen- and table-ware, where safety may also therefore be compromised.

2. The positive authorised list approach and lack of focus on the final article

While many consider positive authorised lists as advantageous, since they limit the use of substances only to those identified and scrutinised by public authorities, they also bring practical problems and limitations. The Regulation of the positive authorised list of starting substances and compositional requirements for plastic FCMs has led to extremely complex technical rules, practical problems in implementation and management and excessive burdens for public authorities and industry alike. The creation of lists causes a significant obstacle to harmonisation of rules for other materials such as inks, rubbers and adhesives. At the present capacity of risk assessments and subsequent EU authorisation it would take around 500 years to assess all substances used in non-harmonised FCM. This does not take into account the need to re-evaluate certain substances when new scientific information becomes available, or that EFSA evaluates the safety of substances increasingly specific to only one use. Increasing scientific knowledge and understanding of FCMs also shows that assessments, which are limited to the starting substances, do not sufficiently address the safety of the final product, including impurities and substances formed adventitiously during the manufacturing process. Consideration of the actual potential use and lifespan of the final article and consequences of the aging of the material is also lacking. As a result, the approach puts a disproportionate emphasis on starting substances, leaving the safety of the final material for the supply chain to resolve without clear rules.

3. Lack of prioritisation of the most hazardous substances and up-to-date assessments

The current EU legislative approach does not consistently prioritise the most hazardous substances in all FCMs. The current evaluation as well as other reviews carried out by the Commission including the Fitness Check of the most relevant chemicals legislation (excluding REACH), highlights the lack of coherence in taking a more precautionary approach to regulating particular groups of substances compared with other EU consumer products legislation. The Chemicals Strategy gives a clear commitment to take a more generic approach to regulating FCM substances whose properties give rise to the greatest concern, such as carcinogenic, mutagenic and reprotoxic substances (CMRs), those that act as an endocrine disruptor (ED) and those that are persistent and bioaccumulative (PBTs and vPvBs). In accordance with the Strategy, the extension of this approach to other chemicals with specific harmful properties should also be assessed. The current FCM framework lacks a mechanism to swiftly take into account new scientific information for example, relevant data that may be available under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation. There is also a lack of coherence in risk assessment work for the same or similar groups of substances assessed by other agencies such as the European Chemicals Agency (ECHA), which would justify the need for an improved “one substance, one assessment” approach. According to EFSA, further, risk assessments also need to be more refined to improve protection of vulnerable groups, which supports actions proposed in the Chemicals Strategy.

4. Exchange of safety and compliance information in the supply chain is poor and the ability to ensure compliance is compromised

In addition to physical sampling and analysis, compliance documentation is crucial for establishing the safety of the material, which details the work undertaken by industry to ensure the safety of the FCM. This exchange of information in the supply chain is also insufficient and not transparent enough to allow all businesses throughout the supply chain to ensure the final product is safe for the consumer and for Member States to check this with the current paperwork-based system. The legislation would therefore benefit from integration of a more modern, simplified and digitalised system commensurate with progressing technological and IT standards, to improve accountability, information flow and compliance work.

5. Enforcement of rules on FCMs is generally poor

Several reasons can be attributed to difficulties encountered by EU Member States in enforcing FCM rules. Evidence from the evaluation shows that primarily these relate to both the lack of clear rules for non-plastic materials and the requirement to control the current EU specific rules, which are too technical, burdensome and challenging for most Member States, who currently have neither sufficient resources nor expertise to enforce the current rules. The assessment of compliance documentation takes expertise and non-compliances found on this basis are difficult to defend in court. Current enforcement therefore relies heavily on analytical control of migration limits. However, accredited methods are currently available for approximately only 20 substances out of around 400 for which there is a migration limit. In general, controls on FCMs are not a high-priority for Member States. This leaves a gap in the regulation and enforcement of many FCMs on the market. This is also highlighted by recent fact-finding and audit work undertaken by the Commission and associated enforcement workshop report. To some extent, this gap is filled by large food business operators with enough purchasing power to force their suppliers to comply with their requirements.

6. Rules do not sufficiently take into account the specificity of SMEs

The current system is especially problematic for SMEs. Whereas larger industry players have certain resources to ensure compliance, SMEs do not and have no system on which they can rely. On the one hand, detailed technical rules are too difficult for them to understand in relation to their business. On the other hand, the absence of specific rules means that they have no basis on which to ensure compliance for non-plastic materials or do not have the resources to address multiple rules in Member States and are therefore restricted as regards the extent to which they can market their products across the EU. Furthermore, SMEs generally do not have the resources to make applications for the assessment of substances for authorisation and must therefore rely on those established by larger industry players.

7. Rules do not encourage development of safer and more sustainable alternatives

The CEAP including the EU Plastics Strategy, has set in motion a comprehensive set of initiatives responding to the challenges posed by increasing use of plastic coupled with public concern. These include tackling over-packaging, waste-prevention measures and increasing reuse and recycling. Member States are already introducing bans on single use-plastic packaging, partially as implementation of the Single-Use Plastics Directive (2019/904). However, the current FCM legislation provides little or no basis on which to develop rules that support and encourage sustainable alternatives to packaging or ensure these alternatives are safe. Many legacy materials and substances were authorised based on a less stringent risk assessment, while new materials and substances are subject to a steadily increasing level of scrutiny. This de-incentivises innovation. Moreover, recyclability of all materials and new technologies such as chemical recycling must be addressed in order for the EU to reach its ambitious recycling objectives.

8. The subject matter is not always clear and definitions need to be reviewed

While the current Article 1(2) of Regulation 1935/2004 sets out the scope ('subject matter'), according to the public consultation carried out during the evaluation, around half of consultees that gave an opinion on this issue indicated in particular difficulties in determining whether certain products fall under the scope of the present FCM legislation. This in part stems from the challenges of predicting or monitoring consumer behaviour and use of certain articles. For industry and Member States alike, it has in turn led to certain difficulties on whether particular items placed on the market are subject to the rules, for example whether plastic table cloths require a Declaration of Compliance or not. Further issues that need to be clarified include FCMs that are regulated under other pieces of legislation, for example medical feeding tubes as well as definitions, which some stakeholders also indicated as insufficient or unclear.

Basis for EU intervention (legal basis and subsidiarity check)

The multinational trade in FCMs means different steps of the manufacturing chain are performed throughout the EU and beyond, resulting in cross-EU and international trade of the raw, intermediate and final materials. There is little or no difference between the materials and articles placed on the market from one country to the next.

On the one hand, the multitude of diverging rules introduced by Member States has increased costs for businesses including SMEs and created barriers to trade. On the other hand, many Member States do not have sufficient capacity to act at national level leaving gaps in consumer safety and difficulties for businesses and Member States' authorities to check that materials are safe.

Therefore, as the differences between national laws and administrative provisions concerning the regulation of food contact materials (1) create different levels of safety for consumers, some of which may not be sufficient and (2) hinder the free movement of goods and create unequal and unfair competition, EU action would be justified on grounds of subsidiarity and added-value. The initiative will be based on Article 114 of the Treaty on the Functioning of the European Union, under which the EU can take action to achieve functioning of the internal market, including rules relating to health and safety, the environment and consumer protection.

B. Objectives and Policy options

The overall objective of the new initiative is to build a comprehensive, future-proof and enforceable regulatory

system for FCMs at EU level that fully ensures food safety and public health, guarantees effective functioning of the internal market and promotes sustainability. It will aim at creating equal rules for all businesses, and supporting them in their ability to ensure safety of the final materials and articles. The new initiative should fulfil the commitments of the Chemicals Strategy in banning the presence of the most hazardous chemicals and reinforcing measures to take account of combinations of chemicals. In recognition of the aims of the CEAP, it should, support the use of sustainable packaging solutions, facilitate innovation towards safer, environmentally-friendly, re-usable and recyclable materials, as well as contributing to food waste reduction. The initiative should also empower the EU Member States to enforce the resulting rules efficiently. Rules would apply equally to FCMs imported from third countries and placed on the EU market.

To address the identified problems, a range of different possible measures is under consideration. These possible measures will be evaluated and further consolidated as part of the full impact assessment, following feedback from stakeholders. In the following section, the possible solutions and alternatives have been assembled broadly into two groups that cover all eight of the specific issues identified. The specific issues that the options principally address are indicated in brackets. All of the potential options aim to improve the two main objectives of the current legislation i.e. ensuring consumer safety and the functioning of the internal market, while considering also solutions to the development of safer and more sustainable alternatives, in line with the Farm to Fork and Chemicals' Strategies:

Ensure the safety and sustainability of the final FCM (concerns principally problems 1, 2, 3, 7 and 8)

A. Shifting the focus onto final materials

New EU specific rules would refocus on the safety of the final material and/ or combinations of materials, addressing their full characteristics and therefore all substances that may potentially migrate into food, instead of only starting substances used in the manufacture of FCMs. Rules would legally define the level of safety that needs to be achieved as well as set clear rules on how to achieve this. In support, rules on Good Manufacturing Practices (GMP) would be strengthened and further developed. This would also provide an opportunity to improve clarity of the subject matter and definitions where necessary for the legislative measure.

In addition, general EU rules would set legal requirements as regards what needs to be achieved in order to ensure the safety of the final materials, whereas industry would be required to determine how the goals would be achieved and implement self-regulation guidelines, customised for each of the concerned sectors.

B. Prioritising the assessment and management of substances

As the risks to consumers are ultimately dictated by exposure to the substances present in and migrating from the FCM, the assessment of individual substances or groups of intentionally and non-intentionally added substances would still remain a key component of the overall safety evaluation and risk management outcomes.

A tiered approach would be used to prioritise regulation of substances, according to a number of factors including their identified hazard properties, together with their use, migration potential and eventual exposure. A greater emphasis would also be put on protecting specific groups of the population including pregnant women and children, who may be more sensitive to the effects of certain substances. The potential combination effect of chemicals will also be considered in the safety assessment, in line with the Chemicals Strategy.

Rules would also ensure that risk assessments take account of the most up-to-date available scientific information and are updated and revised appropriately and in a timely manner. In this sense, the proposal would further clarify the respective role of the Agencies (especially EFSA and ECHA) in the assessment of the most hazardous substances, capitalising on data available under REACH and consistent with the 'one-substance, one-assessment' approach being developed under the Chemicals Strategy.

"Tier 1 substances"

The commitments of the Chemicals Strategy will be fulfilled by introducing a generic approach to the assessment and management of those substances with the most hazardous properties, to ensure greater protection of citizens, consistent with other consumer and chemicals legislation. Primarily, such substances would include those that are carcinogenic, mutagenic and reprotoxic ('CMRs'), endocrine disruptors ('EDs') and persistent, bioaccumulative and toxic substances ('PBTs' and 'vPvBs'). Sufficient criteria and information requirements for determining such properties of FCM substances will also need to be determined. Depending on the outcome of the assessment, the same approach may eventually apply to substances affecting other endpoints, as outlined in the Chemicals Strategy. The essential uses of substances in FCMs will need to be defined taking into account the necessity of the final FCM together with replacement possibilities in order to inform on the possibility for exceptional derogations and consistent with the approach resulting from the Chemical Strategy.

"Tier 2 substances"

Substances with other properties of specific concern such as those in nano-form or those migrating in high amounts ('tier 2 substances') would require a safety assessment using available expertise from EU risk assessment bodies as well as those in Member States.

"Tier 3 substances"

For other substances that are more benign and migrate in low amounts, an approach to support and guide

business operators in their risk assessment would be developed, establishing clearly their responsibilities. This industry work would still be subject to scrutiny as part of the information to be presented in the supply chain and to be checked by enforcement bodies.

C. Supporting safer and more sustainable alternatives

In addition to the approaches described above, the Commission would introduce specific rules to ensure that FCMs manufactured from less traditional and potentially more sustainable production sources and methods, such as those using plant or bio-based technology are subject to dedicated and clear rules on safety to incentivise their use. These materials would be assessed with methods that can better take account of their origins and production methods, which are often considered more benign but should still be verified, and potentially benefit from novel scientific approaches.

To further support goals on sustainability, the Commission would expand rules to prioritise and support all forms of safe re-use and recycling, to exclude risks from contamination and to include all recycling technologies. Rules would ensure consistency and coherence with legislation designed to protect the environment from hazardous substances and ensure alternative substances that are more environmentally friendly are also safe for consumers. Acknowledging the essential role that packaging plays in the food supply chain, rules would also support sustainability of food packaging through their entire life-cycle taking into account the overall aim of preventing food waste as indicated in the Farm to Fork Strategy.

Ensure exchange of information in the supply chain, support for SMEs and enforcement of the rules (concerns principally problems 1, 4, 5 and 6)

D. Improving quality and accessibility of supply chain information for compliance and enforcement

To address these issues collectively, the Commission would introduce clear and consistent rules on data requirements and information transfer throughout the supply chain, including a Declaration of Compliance for all FCMs. The information system put in place would be fully digitalised making it easier for businesses, especially SMEs to ensure compliance and for Member States to enforce. This approach would also better ensure compliance of imported materials with the same EU rules.

E. System for ensuring compliance of the final FCM

As an alternative option to a system where compliance checks are performed solely by the Member States' competent authorities, the initiative will look at the possibility of making use in this area of delegated bodies as provided in Article 28 of Regulation 2017/625 (the Official Controls Regulation) and/or of notified bodies tasked with conformity assessment. This would also further facilitate SMEs in their compliance work. This system would be complementary, allowing Member States to maintain overall control of enforcement. Further development of technical standards by the EU-RL or CEN will be explored, particularly where analytical standards are currently missing.

Options

The baseline situation consists of the continuation of the current implementation of the existing rules, mainly focused on plastic FCMs, recycled plastic FCMs, ceramic materials, and to a lesser extent regenerated cellulose film and active and intelligent materials. Other materials would generally continue to be subject to national rules, supra-national standards or industry guidance. This is the situation that is being subject to the ongoing evaluation. This can be seen as an option 0 ("zero"), or no action.

Two fundamental options will be further evaluated during the impact assessment, using the baseline situation as a benchmark. For each of them, attention will be paid to the **feasibility** of the envisaged solutions (*see above, A to E*) and to the extent to which they **solve the issues** identified (*1 to 8*):

- Option 1: Use the current regulatory framework (with Regulation (EC) No 1935/2004 as a cornerstone)
- Option 2: Develop a new regulatory framework, replacing the current Regulation

Sub-options may be developed when performing the impact assessment, which would address some of the problems identified, while not addressing all of them. For example, under option 1, the possibility of expanding EU harmonisation to all types of materials as an answer to issue 1, to be evaluated, alone or in combination with other measures, thus building sub-options, to be further evaluated.

C. Preliminary Assessment of Expected Impacts

Likely economic impacts

The economic impacts will be looked at in greater detail during the impact assessment and compared against data available for the baseline. In general, the following economic impacts can be expected:

- Decreased health costs due to higher standards of protection for consumers and reduced diseases such as cancers;
- Simplification of rules will lead to greater ability of businesses and in particular SMEs to ensure their products are as safe as those produced by larger businesses. This will improve competitiveness and

growth of SMEs;

- Businesses will have one set of rules to follow and will no longer need additional resources to market their products in multiple Member States or be prevented from selling their products in certain Member States. This will therefore lead to increased growth and innovation, particularly for SMEs;
- Harmonisation in the EU market by introducing new specific rules across all sectors will lead to some increased costs initially as sectors adjust to new EU rules. However, it is expected that it will save them money in the long term compared with compliance with different national rules;
- Increased global competitiveness of EU businesses due to higher standards, which tend to be a driver for many third countries in the absence of harmonised global standards;
- Development and growth in materials that support sustainability and related EU initiatives such as the circular economy and non-toxic environment strategies.

Likely social impacts

The primary objective of the proposal is to improve product safety, ensuring that policy is based on the most up-to-date scientific evidence and that citizens are fully protected from harmful chemicals, such as those that are linked with cancer or disruption of the endocrine system. Human health is a fundamental value and an investment in economic growth and social cohesion. Healthy individuals are more likely to be employed, support economic growth and less likely to be socially excluded. Reduction and prevention of diseases such as cancer alleviates burdens on health services and prolongs people's lives and the quality of those lives. Supporting the safety of new food packaging technologies also supports consumer choice and reduction of food waste. Enabling the production of more sustainable materials will benefit society overall.

Likely environmental impacts

The impact assessment will consider how new EU rules on food contact materials, including packaging, can play a role in contributing to the circular economy, plastics strategy and non-toxic environment. As a first step, it will look to improve on any coherence issues with legislation that aims to protect the environment from chemicals, such as REACH. Reduction of waste and support for the use of materials including polymers that can be easily recycled and safely used again as food contact materials will be considered.

Likely impacts on fundamental rights

Integration of required information into a digital/ online platform would need to respect personal data protection.

Likely impacts on simplification and/or administrative burden

The impact of having one set of simplified EU rules to follow, with common reporting electronic formats will reduce burden created by the current baseline of different national legislation and provide a clear basis for all food contact sectors to demonstrate compliance and for national authorities to enforce. Digitalisation of the compliance and enforcement work will also reduce burden and simplify the process. The costs and benefits for Member States and businesses will be estimated as part of the impact assessment.

D. Evidence Base, Data collection and Better Regulation Instruments

Impact assessment

The initiative represents a major legislative proposal by the Commission, with different policy choices to be considered to achieve the aims and objectives. It will have a significant impact and therefore an impact assessment will be prepared to support it. The initiative is likely to have far-reaching impacts on a total EU sector worth approximately €100 billion, including many SMEs and contribute to the health protection of all EU citizens who are users of FCMs.

To complement the evaluation, which will continue to run in parallel, an impact assessment will consider possible policy options for future legislation on FCMs that supports the Commission's policies and ultimately improves food safety and public health and contributes to a smooth functioning of the internal market.

Evidence base and data collection

Although there are no requirements to monitor Regulation (EC) No 1935/2004, considerable information already exists to support the impact assessment. An evaluation of the food contact materials legislation was started in 2018. So far, it has been supported by an external study as well as numerous consultation exercises, including a 12-week open public consultation and an SME panel questionnaire. The vast majority of stakeholders, if not all, have highlighted deficiencies in the functioning of the current legislation as regards either safety or the internal market and support further EU legislation, particularly for non-plastic materials such as printed paper and board. A more harmonised EU approach is also supported by all Member States.

The JRC baseline study, published in 2017 provides a comprehensive picture on the state of play concerning both national legislation, where substantial differences between Member States' rules are identified. In addition, complete absence of rules in some sectors can also be observed. The report also provides a solid overview of the highly complex supply chain yet commonality of FCMs' markets in Europe.

Recent work undertaken by the Commission on other sectorial legislation also indicates possible issues. For

example, the Fitness Check on General Food Law identifies shortcomings in authorisation procedures foreseen in other secondary legislation, including FCMs. The Single Market Strategy cites the need to strengthen the single market for goods and improve the Mutual Recognition principle on which FCMs rely. The study to support the Fitness Check on the most relevant chemicals legislation ("Fitness Check +") highlights issues on coherence of data, science, and risk management procedures and measures, between different regulatory areas including those relating to FCMs.

In 2016, EFSA published an opinion on developments in risk assessment, examining the safety assessment of FCMs. It concluded that more focus is needed on the finished materials and articles as well as non-intentionally added substances generated during the manufacturing process. The current EU legislation needs to be adapted to sufficiently take into account this opinion and improve consumer safety.

In the same year, the European Parliament published a European Implementation Assessment Study on Regulation (EC) No 1935/2004. The study is based on a survey conducted between December 2015 and February 2016, which documents stakeholders' positions on the functioning of the Regulation. The report reflects the same findings in the ongoing evaluation process that a lack of specific measures at EU level for many materials negatively impacts the functioning of the internal market and food safety and stakeholders are in favour of more specific measures at EU level.

Additional data is still required, in particular to compare the possible benefits such as effectiveness and efficiency of new EU rules compared with the current baseline. Further study work will be needed to supplement the existing information and will be done in consultation with relevant stakeholders, including Member States, business operators and consumer organisations.

Consultation of citizens and stakeholders

Consultations will be carried out to engage all relevant stakeholders and seek their opinion on the main policy options and how they would be affected by them.

Relevant stakeholders for which this consultation may be relevant include, but are not restricted to:

- Member States' national authorities including central competent authorities, local or regional enforcement bodies and control laboratories;
- Professional associations for food contact materials businesses including those that represent small and medium sized enterprises (SMEs);
- Professional associations or individuals representing any relevant parts of the supply chain including chemicals industry, importation of goods from third countries and the food industry;
- Individual businesses operators including food business operators, and in particular SMEs and microbusinesses not represented by professional associations;
- The European Parliament;
- EU citizens and members of the general public (consumers);
- Non-governmental organisations (NGOs) including consumer watchdogs;
- Relevant European bodies including the European Food Safety Authority (EFSA);
- Scientific experts relevant to the field of FCMs including those in the field of research or academia;
- Other relevant professional bodies e.g. consultancies, think tanks and law firms.

An extensive consultation process will be undertaken structured around three main axes of actions:

- A 12-week internet based public consultation will take place to ensure transparency and accountability and give any interested party the possibility to contribute. The questionnaire will be available in all official EU languages and the replies can also be submitted in all official EU languages. This is provisionally planned to take place in the second quarter of 2021;
- A set of targeted consultation activities tailored for particular stakeholders' groups, including interviews will be conducted;
- Stakeholder working groups are also foreseen to take place to complement the process, gather views on possible future legislation and ensure that all relevant interested parties are included.

The consultation will be published on the Commission's Have Your Say web page. Further information on the consultation will be published at https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/evaluation_en.

Will an Implementation plan be established?

No implementation plan is foreseen, as the legislation will be in the form of directly applicable Regulation(s).