



ETRMA on the Inception Impact Assessment on the Revision of EU rules on food contact materials (FCMs)

Brussels, 28th January 2021

Industry needs a unique internal market for rubber materials in contact with food. ETRMA welcomes that the announced new EU specific rules will address non-regulated products and it is ready to support and contribute to the development of the new EU specific rules over the coming years.

The EU industry of General Rubber Goods (GRG) includes approximately 6000 companies, most of them SMEs. EU production is estimated around 2.3 million tons of GRG. The food contact materials and drinking water sector accounts for 2% of the total production sector. Rubber uses in food contact material include, the following applications: food transportation (conveyer belts, hoses, tubing, rotating transport rollers and rolling mills); food handling (gloves), machinery components (seals, gaskets, hoses, flexible connectors and diaphragm/butterfly valves); plate heat exchangers and general seals (used in machinery and storage vessels); sealants (can and bottle seals/closures); baby feeding (teats and breast caps); household appliances (including seals in pressure cookers), etc.

We welcome the publication of the Inception Impact Assessment of the Revision of EU rules on food contact materials (FCMs), particularly the announcement to address the situation of materials for which there are no EU specific measures and they remained subjected to national measures. Indeed, rubber materials in contact with food suffer from different implementation measures of the FCM regulation across EU Member States.

Several EU Member States - France, Germany, Italy, The Netherlands or Spain - have adopted specific regulations for rubber in food contact materials. The content of the positive lists and the provisions varies from country to country. This situation leads to obstacles for the internal market and additional burden for companies. We estimate the costs to certify a rubber FC product at several thousands of euros for each Member State.

In addition, compliance and enforcement of the current regulation is poor and not fully implemented, risking that non-compliant products are on the market. This compromises the health and the safety of consumers, and threatens the level playing field for those that fully comply.

ETRMA would like to share the following considerations:

There is a need to assess what could be the best solution for the rubber industry, a European-harmonized positive list cannot be discarded at this stage.

There are several positive lists of substances approved across national regulations, for rubber goods, more than 8 countries have a positive list for rubber defined¹. The use of positive lists is known by producers of rubber goods in Europe and has proved to be easy to understand for rubber manufactures, costumers and produces of final complex products.

¹ CZ, DE, ES, FR, HR, IT, NL, SK, Source: Study supporting the Evaluation of Food Contact Materials (FCM) legislation - (Regulation (EC) No 1935/2004), July 2020, Ecorys.



Ecorys study² also stresses the importance of positive lists, for specific sectors, such a rubber:

“According to the consultation implemented in this study, five main materials are considered a priority by stakeholders: printing inks, paper and board, silicones, varnishes and coatings, and rubber. Positive lists already exist in several Member States for these materials and there is extensive knowledge on these substances within the industry”.

Industry is SME’s driven, suppliers and producers are used to the implementation of positive lists. At this stage, it is difficult to see whether a change from a positive list to a non-positive list system will affect the rubber value chain.

ETRMA would like to work together with the European Commission, Members States Competent Authorities and value chain partners to build a future system.

Migration from rubber matrices differs from other organic materials.

The announced new EU specific rules would aim to build new *Rules that would legally define the level of safety that needs to be achieved as well as set clear rules on how to achieve this*. When drafting the rules it shall be noted that **one-fits-all solution for organics materials will not address adequately rubber specificities**. Rubber specificities shall be taken into account particularly in the use of specific simulants that mimic rubber migration.

ETRMA shares the need to reduce the presence of hazardous substances and set strict requirements for its use.

ETRMA agrees on the principle to reduce or eliminate the use of hazardous substances in rubber products. This is a principle we have been following for many years. Nevertheless, we must take into account technical and performance reasons, that could request hazardous substances, whose use is to be considered essential. Therefore, a risk assessment approach with solid technical evaluation on performance requirements has to be followed, with the respect of safe thresholds for migration, in accordance with article 3 of the FCM regulation.

ETRMA shares the need to address the potential environmental impact of food contact materials. However double regulation shall be avoided.

ETRMA shares the need to take into consideration not only the safety aspects, but also sustainability aspects, such as environmental impacts, circular economy, in accordance to the Green Deal. However, these topics are already subject to specific regulations, that must be followed, without any further addition.

European Tyre and Rubber Manufacturers’ Association members (www.etrma.org).

ETRMA represent 93 tyre manufacturing plants spread across EU28, Turkey and other candidate countries employing some 200.000 direct jobs in the tyre sector. ETRMA, represents more than 6.000 companies in EU28, employing 360.000 individuals and supports another 800.000 jobs in related sectors. The product range of its members is extensive from tyres to pharmaceutical, baby care, construction and automotive rubber goods and many more applications. ETRMA members’ turnover in 2016 is approximately € 73 billion, of which up to 5% continues to be invested in R&D, annually. ETRMA’s membership include the following tyre manufacturers: APOLLO VREDESTEIN, BRIDGESTONE EUROPE, BRISA, COOPER TYRES, CONTINENTAL, GOODYEAR EUROPE, HANKOOK, MARANGONI,

² Study supporting the Evaluation of Food Contact Materials (FCM) legislation - (Regulation (EC) No 1935/2004), July 2020, Ecorys.

MICHELIN, NOKIAN TYRES, PIRELLI, PROMETEON, SUMITOMO RUBBER INDUSTRIES AND TRELLEBORG WHEEL SYSTEMS. Furthermore, members include Associations in the following countries: Finland, France, Germany, Hungary, Italy, the Netherlands, Poland, Spain and the UK.

