



Raising standards for consumers

POSITION PAPER

NEED FOR CONSISTENT REGULATION OF MATERIALS IN CONTACT WITH FOOD

ANEC contribution to European Commission's
evaluation of legislation on
Food Contact Materials



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SUMMARY

This ANEC position paper is developed as a contribution to the DG SANTE public consultation evaluating legislation on Food Contact Materials. We reiterate our call to strengthen the regulatory framework for food contact materials by:

- excluding certain substances of high concern (such as CMRs) in all food contact materials in the Framework Regulation for materials in contact with food (Regulation (EC) No 1935/2004) using a strict limit;
- reviewing existing implementing measures with a view to filling existing gaps and adapting the measures to the state-of-the-art;
- introducing specific measures for all materials listed in Annex I to the Framework Regulation not yet covered by regulatory provisions.

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INTRODUCTION

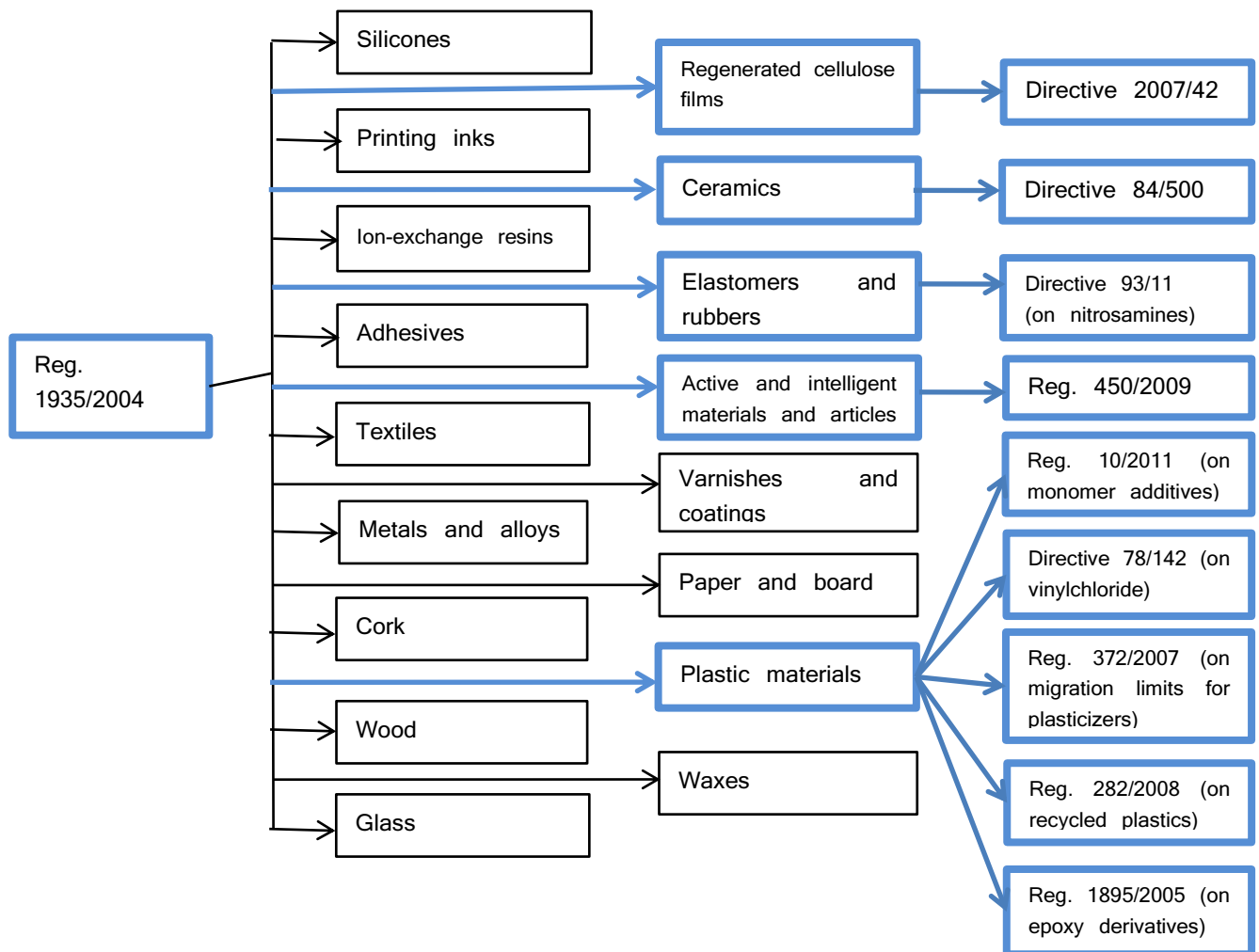
We believe the questions in the public consultation on the evaluation of legislation on food contact materials will allow interesting data to be collected on the experiences of consumers, and stress their lack of awareness of the safety of food contact materials and their labelling. However, the questionnaire does not facilitate the contribution of proposals to improve the safety of food contact materials, or their assessment.

Hence we use this paper as a reminder of the shortcomings we believe exist in the current European regulatory framework and to put forward recommendations on the EU policy actions that should be taken.

1 | Deficits in FCM regulation

Regulation (EC) No 1935/2004, on materials and articles intended to come into contact with food, is the framework regulation that sets out general requirements for all food contact materials. Only a few measures are harmonised at EU level though, and this lack of harmonised rules puts at stake the safety of materials that come in contact with consumers' food. The regulation lacks important provisions, such as a general exclusion of CMR substances (unless authorised in an implementing measure) or other substances of concern (e.g. SVHCs other than CMRs included in Annex XIV of REACH) which should apply to all food contact materials.

For the group of materials and articles listed in Annex I of the Regulation, specific measures may be adopted or amended by the European Commission (EC) using a Comitology procedure. In fact, implementing measures have been adopted for only a few materials, as shown in the picture below (blue framed boxes).



- Only **plastics materials** are comprehensively regulated (Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food), but there are still gaps that need to be closed (i.e. colorants, solvents and aids to polymerisation are not yet regulated). From a consumer perspective, it is welcome that plastics materials are regulated by means of a positive list (authorisation list), i.e. only approved substances are allowed to be used. A comitology procedure also allows limits to be established in a rather flexible way. A further welcome aspect is that nanomaterials need an explicit authorisation. However, the list of authorised substances included in its Annex I seems partly outdated and needs more systematic maintenance and review.
- The implementing measure on **ceramic articles** (Council Directive 84/500) needs updating as regards the limits for the release of lead and cadmium. The current limits are completely outdated. Provisions for further relevant elements are missing and should be introduced. The EC started a discussion process in 2012, and in 2017 the debate on scope and limits in the measure was reopened

with Member States, investigating the validity of the methods to regulate these FCMs and presence of heavy metals.

- The implementing measure in the field of **elastomers and rubbers** covers only the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers (Commission Directive 93/11). However, there are many more substances used (or formed) in the production of rubber that are of concern and should be addressed.

Several organisations active in ANEC found harmful chemicals in products that come into contact with food, such as pizza boxes, non-stick pans, beverage packaging, silicone bakeware, and advent calendars with chocolates.

It is also alarming that some substances of high concern are addressed only in a generic manner in legislation. The regulatory standstill in this field at the EU level could lead to an adverse effect on the functioning of the internal market.

The deficits of the Regulation are well known and have been debated for some time. In July 2012, EC published a "Roadmap"¹ entitled, "Food Contact Materials - Specific provisions for materials other than plastics – implementing measure". It states: "*Recent food scarce originating from food packaging led to criticism by Member States, Industry and the European Parliament on the lack of EU specific legislation for materials other than plastics*". The Roadmap is intended to "focus on the safety of these other materials and in particular those for which there is a high risk from transfer of its constituents into food (printing inks, coatings, silicones, adhesives, rubber, metals, paper and board and combinations of materials).

In 2017, the EC issued a new Roadmap for evaluation of FCMs regulation, following the JRC Baseline study². Although it is welcome that the EC also reopened the debate on the revision of the measure on ceramics, and on further measures on some aspects such as printed food contact materials and mineral oil hydrocarbons, the EC failed to take appropriate action and no real progress was made. A systematic approach to priority products is missing.

The 2016 European Parliament assessment study already found relevant stakeholders, as well as Member States' competent authorities, to be in favour of specific measures at EU level for the FCMs that are not yet harmonised at EU level. The study, similarly to the 2017 JRC Baseline study on non-harmonised food contact materials in the EU: Regulatory and market situation, also confirmed the lack of specific measures at EU level for some food contact materials/articles negatively impacts the functioning of the internal market for the relevant material/article and its food safety.

¹ <http://tinyurl.com/p99a97d>

² 2017 JRC Baseline study on non-harmonised food contact materials in the EU: Regulatory and market situation <https://tinyurl.com/y4qhdp2>

Moreover, the European Parliament Resolution on implementation of the Food Contact Materials Regulation (EC) No 1935/2004 ([2015/2259\(INI\)](#)), given the prevalence of FCMs on the EU market and the risk posed to human health, asks the EC to prioritise the drawing up of specific measures for paper and board, varnishes and coatings, metals and alloys, printing inks and adhesives. It also asked for a ban on Bisphenol A, and for a coherent regulatory approach on CMR substances and other substances of concern. ANEC applauded the report's essence and key conclusions.

ANEC calls on the EC to act immediately and to propose implementing measures at least for some priority materials (including printing inks, paper and board, metals and coatings). In the long run, approval systems (as in case of plastic materials) should be foreseen. However, as an interim measure, substance exclusions could be foreseen and be adopted rather quickly.

European rulemaking in this field could be based on existing national rules³ (some Member States, such as The Netherlands, have comprehensive legislation in place). In addition, a report of the EFSA Scientific Cooperation (ESCO) Working Group⁴ gathered and analysed information about substances identified in FCM other than plastics. It includes an inventory list of about 2.800 substances. However, a more comprehensive assessment is available for only a fraction of them. Several recommendations of the Council of Europe⁵ may also be useful sources of information for developing EU rules for non-plastics FCMs.

Moreover, other aspects should be covered. In particular, we believe non-intentionally added substances (NIAS) deserve particular attention. Clear rules and thresholds for such substances must be established.

2 | ANEC proposals to enhance FCMs' safety

ANEC proposals for food contact materials:

- A general ban of substances which meet the criteria to be classified as CMR (category 1A, 1B and 2) and other substances of concern (such as SVHCs, other than CMRs included in Annex XIV of REACH or certain categories of EDCs once such categories have been adopted) shall be included in the Framework Regulation for materials in contact with food (Regulation (EC) No 1935/2004)

³ <http://tinyurl.com/ps6z29q>

⁴ <http://tinyurl.com/o38g8up>

⁵ <http://tinyurl.com/n9wwlr2>

for all FCM materials including a strict limit (e.g. migration limit of 10 ppb). Derogations may be adopted based on assessments by EFSA.

- The implementing measure on ceramics (Council Directive 84/500) needs to be updated as quickly as possible with a view to reducing the limits for cadmium and lead release, and incorporating further elements.
- The gaps in the implementing measure on plastics materials (Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food), i.e. colorants, solvents and aids to polymerisation, shall be filled.
- The only implementing measure in the area of elastomers and rubbers covers solely the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers (Commission Directive 93/11). However, there are many more substances used or formed in the production of rubber that are of concern and should be addressed, particularly in products for small children.
- A list of top priority materials for regulation needs to be established and shall include at least printing inks, paper & board, metals & alloys and varnishes & coatings for the time being. However, preparatory work for addressing other materials should be started as well to ensure that eventually all materials are covered.
- For the priority materials, new implementing measures shall be adopted based among others on existing national regulations, the ESCO report and the statements by the Council of Europe.
- Where feasible the same approach as for plastics FCMs shall be used for the selected priority materials, i.e. an approval system for substances allowed to be used complemented by specific content and/or migration limits.
- Substances in nanoform shall be separately assessed from their bulk forms, i.e. approval of the bulk material shall not mean endorsement of the nanoform.
- Where an approval system is used, transitional arrangements will have to be made as the establishment of positive lists will take many years. For some materials, this approach may not be feasible or practical. In such cases the most relevant contaminants relating to a particular material shall be identified and restricted (e.g. limitation of mineral oil in paper and board).
- Non-intentionally added substances (NIAS) deserve particular attention. Clear rules and thresholds for such substances must be established.

3 | EXPECTATIONS FROM THE FCM EVALUATION

ANEC calls on the EC to address the deficiencies in the implementation of the Food Contact Materials Regulation (EC) No 1935/2004 as quickly as possible, considering the recommendations we make above.

As we highlight, this urgency is supported by a wide range of stakeholders, including the European Parliament and national competent authorities. The EC is now expected to take further action. Inactivity and further delays are not acceptable.

We call on the EC to act quickly to fill gaps in the existing measures, and introduce implementing measures for all materials listed in Annex I to the Framework Regulation not yet covered by regulatory provisions, starting with priority materials (including printing inks, paper and board, metals and coatings).

ANEC also asks to exclude CMRs and other substances of high concern in all food contact materials. As an interim measure, substance exclusions could be foreseen and adopted rather quickly. In the medium and long term, approval systems should be foreseen, as for plastics materials.



ANEC is the European consumer voice in standardisation, defending consumer interests in the processes of technical standardisation and the use of standards, as well as related legislation and public policies.

ANEC was established in 1995 as an international non-profit association under Belgian law and is open to the representation of national consumer organisations in 34 countries.

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