



Raising standards for consumers



POSITION PAPER

on the implementation of the Food Contact Materials Regulation (Regulation (EC) No 1935/2004)

**Input to the DRAFT European Parliament Report (2015/2259(INI))
developed in Committee on Environment, Public Health and Food Safety.
Rapporteur: MEP Christel Schaldemose**

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Abstract

The ANEC position paper reiterates its call expressed in the past 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 to 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.

ANEC very much welcomes the "[**Draft report on the implementation of the Food Contact Materials Regulation \(Regulation \(EC\) No 1935/2004\) \(2015/2259\(INI\)\)**](#)¹" for the Committee on the Environment, Public Health and Food Safety by Rapporteur MEP Christel Schaldemose. The general spirit and several major conclusions of this draft report are very much in line with the position of ANEC. However, we suggest some of its recommendations are revisited as outlined in section 3 of this paper.

Based on ANEC views on FCM legislation, concrete amendments are suggested in section 4 of this position paper, specifically relating to the part "Implementation of EU legislation on FCMs successes and gaps" of the ENVI draft report.

¹ <http://tinyurl.com/h7bnsqj>

1. Background

In June 2014, ANEC published its position paper '[Hazardous chemicals in products. The need for enhanced EU regulations](#)' which included an analysis of shortcomings in the current European regulatory framework concerning chemicals in consumer products and called for the development of a systematic approach focusing on sectoral regulatory action to compensate for the deficiencies identified. It was found that current provisions are flawed because of serious constraints (gaps, lacking limit values or low level of protection) or are missing altogether.

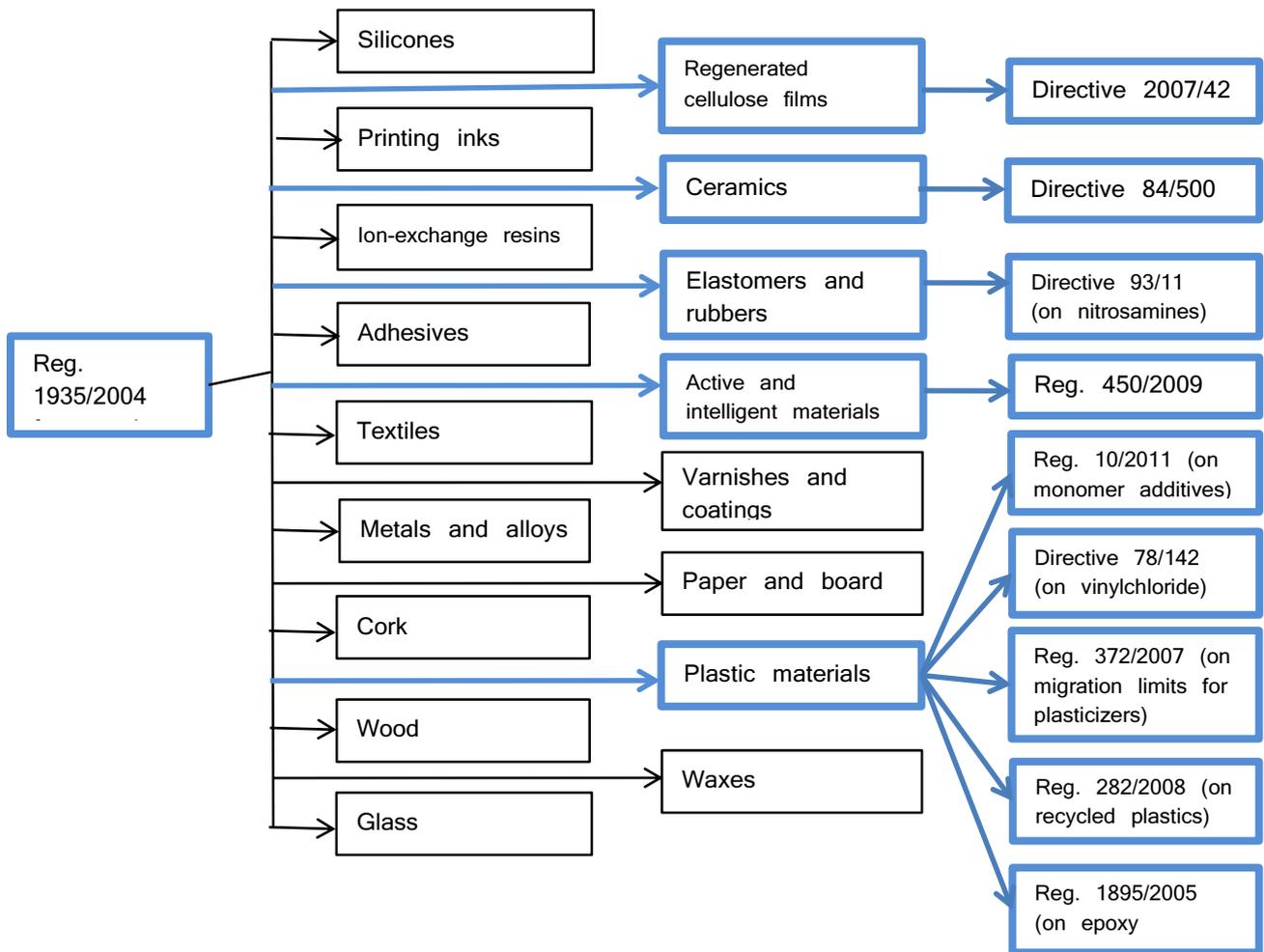
REACH does not, and will not, compensate for these inadequacies because articles – particularly imported ones – are barely covered. Moreover, the process of restriction is related to (comprehensive) single substance risk assessments which are laborious requiring a high resource input. Consequently, the process is extremely slow. And inefficient. For example, generic bans of all CMR (carcinogenic, mutagenic or toxic for reproduction) substances in articles cannot be established. Further, an approval system for chemicals in articles – similar to the positive lists in cosmetics and food contact legislation – is not possible within REACH. Non-toxic effects or parameters (e.g. organoleptic parameters, such as smell or taste) cannot be addressed either.

Materials in contact with food were identified as an area for which – as a matter of highest priority – (enhanced) requirements must be adopted. In ANEC's view the regulatory action should be initiated immediately and cover the issues described in the following section.

2. ANEC position on FCM legislation

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. It contains general safety requirements and provides that food contact materials must not transfer their components into food in quantities that could endanger human health, change food composition in an unacceptable way or deteriorate its organoleptic properties (taste, colour and odour). The framework 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 Commission 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 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 Commission started a discussion process in 2012 but there does not seem to be any progress.

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.

The deficits of the regulation are well known and have been debated for some time. In July 2012 the Commission published a "Roadmap"² 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). However, the foreseen Impact Assessment which was envisaged to be initiated in September 2012 has not taken place. It is a shame that the Commission has obstructed this important project despite strong support from a broad range of stakeholders. ANEC calls upon the Commission 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 can 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 partly evaluated by Member States. It includes an inventory list of about 2800 substances. However, a more comprehensive assessment is available only for a fraction of them. Several recommendations of the Council of Europe⁵ may also be a useful source of information for developing EU rules for non-plastics FCMs.

Apart from the issues mentioned above additional aspects should be covered. In particular, ANEC believes that non-intentionally added substances (NIAS) deserve particular attention. Clear rules and thresholds for such substances must be established.

² <http://tinyurl.com/p99a97d>

³ <http://tinyurl.com/ps6z29q>

⁴ <http://tinyurl.com/o38g8up>

⁵ <http://tinyurl.com/n9wwlr2>

ANEC proposals for non-plastics 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 scientific criteria are made available by the Commission) shall be included in the Framework Regulation for materials in contact with food (Regulation (EC) No 1935/2004) for all FCM materials including a strict limit (e.g. 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 just 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 other 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. European Parliament draft own-initiative report

ANEC very much welcomes the draft report on the implementation of the Food Contact Materials Regulation (Regulation (EC) No 1935/2004) prepared for the Committee on Environment, Public Health and Food Safety by Rapporteur Christel Schaldemose. The general spirit and several major conclusions of this draft report are very much in line with the position of ANEC. However, we have suggestions on where some of its recommendations should be revisited as outlined below.

Gaps and priority implementing measures

ANEC agrees entirely that *"the major focus should be on the adoption of specific measures for those 13 materials not yet regulated at EU level"*. The report considers that *"the Commission should prioritise the drawing-up of specific EU measures for paper, board, coatings, inks and adhesives"*.

Whilst ANEC concurs with the selection of paper & board, coatings and inks we believe that metals are to be seen also as priority item. The study on the implementation of Regulation (EC) No 1935/2004 'European Implementation Assessment'⁶ by the European Parliament's Research Service (DG EPRS) published in May 2016 (and mentioned in the Explanatory Statement of the Schaldemose draft report) indicates a different priority list by the stakeholders involved in the survey. It includes a graph with preferences expressed by the stakeholders on page 59 (Graph 2). The categories paper & board, printing inks, varnishes and coatings and metals & alloys was supported by more than 40% of the participants.

We think that the report of the EU Parliament should reflect the priorities expressed by stakeholders in its own research work. This does not preclude a broadening of the list of priority items. After all, we see the risk that prioritisation of some materials could push aside all others. Hence, ANEC thinks that a clear message must be given that sooner or later implementing measures for all materials should be adopted and work in support of this should be commenced also for non-priority items.

ANEC believes that the approach followed in the implementing measure for plastics materials (authorisation) should be followed, where feasible also when other

⁶ <http://tinyurl.com/hu8smga>

materials are regulated. We understand that this may be time consuming and not practical in some cases. Nevertheless this approach should be given priority although in the short term other approaches using substance exclusions may be needed on an interim basis.

Legislation in place

ANEC agrees that "*shortcomings exist in the implementation and enforcement of the legislation in place*". The draft report rightly points to shortcomings related to Declarations of Compliance (DoC) and enforcement and controls by Member States. However, ANEC thinks that there are also other deficits in the existing rules. One important issue is already mentioned in the draft report: that substances classified as SVHCs under REACH may still be used in FCMs. This requires in ANEC's view a legislative change in the FCM framework regulation. ANEC thinks that there should be a general exclusion 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, possibly also certain classes of EDCs in future once scientific criteria are available) for all FCM materials including a limit (e.g. 10 ppb). Derogations may be adopted based on advice by a scientific committee.

Further, ANEC considers that some of the existing implementing measures are completely outdated (ceramics) or incomplete (ceramics, rubber) and urgently need to be updated and broadened. Also the implementing measure on plastics materials has gaps (e.g. colourants, solvents) and its Annex I including authorised substances and seems partly outdated and needs more systematic maintenance and review.

4. Proposed changes

ANEC proposes the following amendments:

Implementation of EU legislation on FCMs successes and gaps

2. Underlines that, while the major focus should be on the adoption of specific measures for those 13 materials not yet regulated at EU level, shortcomings exist in the regulatory provisions, implementation and enforcement of the legislation in place;

4. Believes that, given the prevalence of the materials referred to on the EU market and the risk they pose to human health, the Commission should prioritise the drawing-up of specific EU measures for paper, board, varnishes & coatings, inks and metals & alloys adhesives at this stage;

New 4a: Stresses that the need for specific measures also for the other materials listed in Annex I to the Framework Regulation should be carefully investigated;

New 4b: Considers that the authorisation approach (positive list) followed in the implementing measure for plastics materials should be considered, where feasible and practical, also when specific measures for other materials are prepared;

New 4c: Believes that nanomaterials should be subject to authorisation not only in plastics materials but in all FCM materials and shall be separately assessed from their bulk forms;

New 4d: Proposes to review and revise the regulatory provisions of the existing FCM legislation

- to ensure that 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 in future once scientific criteria are available) are banned in all FCM materials with a possibility to adopt derogations;
- to revise, as a matter of priority, the implementing measure on ceramics (Council Directive 84/500 with a view to reducing the limits for cadmium and lead release and incorporating further elements;
- to fill the gaps in the implementing measure on plastics materials (Commission Regulation (EU) No 10/2011), i.e. to include provisions for colorants, solvents and aids to polymerisation and to review the validity of the provisions given in its Annex I;
- to address substances of concern used or formed in the production of rubber and other elastomers other than those covered in the implementing measure concerning the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers (Commission Directive 93/11), particularly in products for small children.

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About ANEC

ANEC is the European consumer voice in standardisation, defending consumer interests in the processes of technical standardisation and conformity assessment, 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 32 countries.

ANEC is funded by the European Union and EFTA, with national consumer organisations contributing in kind. Its Secretariat is based in Brussels.



Raising standards for consumers

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