Evaluation of Food Contact Materials legislation

Fields marked with * are mandatory.

Introduction

Food Contact Materials (FCM) includes all food packaging as well as kitchenware, tableware and food appliances such as cutlery, cups, plates, bowls etc. It may also include articles which were not originally intended for food contact but which may nevertheless foreseeably come into contact with food, such as paper napkins. Furthermore, FCM covers materials used in professional food manufacturing, preparation, storage and distribution – from chocolate conveyor belts to milk tankers. Many different types of material may be used to make FCM including plastic, paper, rubber, metal and glass but also adhesives, printing inks and coatings used in the finishing of the final articles, as well as composite materials.

Example of food contact materials (FCMs), clockwise from top-left: Plastic tray and cling film packaging used to wrap apples; printed paper packaging used to wrap butter; re-usable plastic boxes for storing food; cutlery made from bamboo

EU legislation on FCMs requires businesses to manufacture FCMs so that under intended or foreseeable use they do not endanger human health or bring about an unacceptable change in the composition or deterioration in the organoleptic properties – taste and smell, for example – of the food.

The Regulation concerns only the safety of the FCM as regards the transfer of chemicals into the food from the FCM. The rules do not set any hygienic requirements for FCM; nor do they cover the waste or
environmental impact of FCMs, which are dealt with under other EU legislation.

The Regulation also aims to ensure the effective functioning of the European Union market i.e. to avoid restrictions or tariffs.

You can find out more information on our website at https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials_en.

WHAT IS THIS QUESTIONNAIRE ABOUT?
This questionnaire is part of a consultation exercise being undertaken to gather the views and in particular evidence from a wide range of stakeholders on the functioning of the FCM legislation as part of an ongoing evaluation exercise. As the legislation is aimed at protecting consumers, Part I of the questionnaire is particularly important, to obtain direct views from citizens, as consumers.

INFORMATION ON THE QUESTIONNAIRE.
This Online Public Consultation questionnaire is structured as follows:

- **Introduction**: This part will ask you to provide information about yourself.
- **Part I**: The second section is addressed to citizens. Respondents should ideally not have any specialist knowledge on food contact materials.
- **Part II**: This part is addressed to experts or those with prior knowledge of the FCM legislation and working in the field. Some additional questions also exist depending on the type of organisation that you are responding on behalf of.

Part I of the questionnaire for citizens only should take you no more than 15 – 20 minutes to complete. Part II of the questionnaire for those with knowledge of FCMs, including organisations, businesses, and public authorities should take no more than 30 minutes to complete.

Fields marked with * are mandatory.

THE RESULTS
The consultation period will last 12 weeks. Once the evaluation of the FCM legislation is completed, a synopsis report off all consultation activities will be published on the consultation page.

YOUR OPINION REALLY MATTERS
Thank you in advance for taking the time to contribute to this consultation.

About you

*Language of my contribution
- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- English
- Estonian
I am giving my contribution as
- Academic/research institution
- Business association
- Company/business organisation
- Consumer organisation
- EU citizen
- Environmental organisation
- Non-EU citizen
- Non-governmental organisation (NGO)
- Public authority
- Trade union
- Other

If you are a Public enforcement laboratory, please select ‘Other’ and then confirm your identity

* First name

Sidsel

*Surname

Dyekjaer

*Email (this won't be published)

sidsel.dyekjaer@chemtrust.org

*Organisation name
CHEM Trust

* Organisation size
  - Micro (1 to 9 employees)
  - Small (10 to 49 employees)
  - Medium (50 to 249 employees)
  - Large (250 or more)

Transparency register number

Check if your organisation is on the transparency register. It's a voluntary database for organisations seeking to influence EU decision-making.

27053044762-72

* Country of origin

Please add your country of origin, or that of your organisation.

- Afghanistan
- Åland Islands
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Barbados
- Bangladesh
- Bahamas
- Bahrain
- Bangladesh
- Barbados
Part II – Stakeholders answering as experts or with knowledge in the field

The following question concerns the scope and general requirements of Regulation 1935/2004, taking into account Articles 1, 2 and 3

To what extent do you agree with the following?

5 = strongly agree; 4 moderately agree; 3 neither agree nor disagree; 2 moderately disagree; 1 = strongly disagree

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<tr>
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<th>No opinion</th>
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<tbody>
<tr>
<td>*The scope of Regulation 1935/2004 is sufficiently clear and it is always obvious whether a product is an FCM (food contact material) or not</td>
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<td>*The definitions are sufficient and clear</td>
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<td>*The term ‘normal or foreseeable conditions of use’ is clear and interpreted equally by everyone, and the way in which consumers may use or re-use FCMs is sufficiently taken into account</td>
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<td>*Businesses ensure compliance with the general safety requirements in Article 3</td>
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<td>*The labelling, advertising or presentation of FCMs does not mislead consumers</td>
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The following question concerns Good Manufacturing Practice (GMP) laid down in Commission Regulation (EC) No 2023/2006

To what extent do you agree with the following?

5 = strongly agree; 4 moderately agree; 3 neither agree nor disagree; 2 moderately disagree; 1 = strongly disagree

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<tr>
<td>* The objectives and rules on GMP are sufficiently detailed and effective in ensuring that FCM are manufactured to a high standard</td>
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<tr>
<td>* GMP is implemented effectively in the EU ensuring that FCMs are manufactured to a high standard</td>
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<td>* GMP is implemented effectively in the third countries (countries exporting to the EU) ensuring that FCMs are manufactured to a high standard</td>
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The following question concerns labelling requirements, set out in Article 15 of Regulation and the following symbol in annex II of Regulation 1935/2004

To what extent do you agree with the following?

5 = strongly agree; 4 moderately agree; 3 neither agree nor disagree; 2 moderately disagree; 1 = strongly disagree

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<th>No opinion</th>
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<tr>
<td>* The labelling requirements set out in Article 15 are sufficiently detailed and effective at ensuring the safe use of FCMs by consumers</td>
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<td>* The labelling and instructions placed on FCM by businesses are sufficiently detailed and effective in ensuring the safe use of the final article</td>
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<td>* The labelling requirements set out in Article 15 are effectively controlled and enforced by Member States</td>
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* Consumers understand the FCM symbol in annex II and it is an effective way at communicating to them that the product is safe to use as a FCM

* When a product is not labelled with the FCM symbol in annex II, and not otherwise labelled as suitable for foods, consumers know it is not for food use

The following question concerns traceability requirements, in particular as regards Article 17 of Regulation 1935/2004

To what extent do you agree with the following?

5 = strongly agree; 4 moderately agree; 3 neither agree nor disagree; 2 moderately disagree; 1 = strongly disagree

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* Traceability requirements are sufficiently detailed

* Traceability requirements are effective in facilitating the control and recall of FCMs, attribution of responsibility and information for consumers

* Traceability is ensured in the FCM supply chain at all times

The following question concerns the controls, enforcement and sanctions carried out under the FCM legislation, in particular as regards Articles 24 and 25 of Regulation 1935/2004 as well as the requirements of Regulation (EC) No 882/2004 on official controls.

To what extent do you agree with the following?

5 = strongly agree; 4 moderately agree; 3 neither agree nor disagree; 2 moderately disagree; 1 = strongly disagree

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* There are sufficient controls and enforcement carried out in the EU on FCMs, including Article 3

* There are sufficient resources including expertise in Member States to carry out inspection and controls

* There is sufficient access to analytical methods used to verify compliance with compositional requirements

* Sanctions for non-compliance are consistent across Member States

* Sanctions for non-compliance are sufficiently dissuasive
* The legal provisions set out under FCM legislations provide legally robust justification of sanctions

* The safety of FCM sold over the internet is effectively controlled

The following question concerns the absence of specific EU measures under Article 5 and/or presence of national measures under Article 6.

To what extent do you agree with the following?

5 = strongly agree; 4 moderately agree; 3 neither agree nor disagree; 2 moderately disagree; 1 = strongly disagree

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<th>Statement</th>
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<tr>
<td>* Member States' rules are sufficiently detailed and effective at ensuring safety for consumers in the absence of EU specific measures</td>
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<td>* Applicable national rules in the absence of EU specific measures, including authorised substances, migration limits and test methods are consistent</td>
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<td>* The application of the Mutual Recognition principle functions well in the area of FCM</td>
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<td>* There is an agreed and common approach to the risk assessment of FCM which results in similar risk management</td>
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<td>* Member States’ risk assessments carried out on substances or materials which are not authorised at EU level are effective at ensuring safety</td>
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<td>* Industry self-regulation for materials which are not authorised at EU level is effective at ensuring safety</td>
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<td>* Industry self-regulation for materials which are not authorised at EU level is effective at ensuring effective functioning of the market</td>
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The following question concerns specific EU measures under Article 5 of Regulation 1935/2004, Article 16 on Declaration of Compliance (DoC) as well as Commission Regulation (EU) No 10/2011 on plastic FCMs.

To what extent do you agree with the following?

5 = strongly agree; 4 moderately agree; 3 neither agree nor disagree; 2 moderately disagree; 1 = strongly disagree
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<tr>
<td><em>The tools provided by Article 5 (a) – (n) (e.g. positive authorised lists) are adequate and sufficient to establish specific measures to achieve the objectives of the legislation</em></td>
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<td><em>The current specific rules on plastic FCMs are sufficient to achieve the safety of the final FCM</em></td>
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<td><em>The current specific rules on plastic FCMs are sufficient to achieve functioning of the internal market</em></td>
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<td><em>It is appropriate to apply specific rules to materials separately, such as plastic rather than to multiple materials or combinations of materials</em></td>
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<td><em>Rules on the Declaration of Compliance and Supporting Documentation are sufficient to ensure compliance in the supply chain</em></td>
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<td><em>Businesses ensure that the Declaration of Compliance supplied to downstream operators contain sufficient ‘adequate’ information to allow them to ensure their FCMs are safe</em></td>
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<td><em>EU guidance is helpful in achieving the objectives of the legislation</em></td>
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The following question concerns the assessment and authorisation of substances under Articles 8 – 12 (e.g. for substances used in plastic FCM under Commission Regulation (EU) No 10/2011).

To what extent do you agree with the following?

5 = strongly agree; 4 moderately agree; 3 neither agree nor disagree; 2 moderately disagree; 1 = strongly disagree.

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<tr>
<td><em>The current EU assessment and authorisation process is effective in ensuring the safety of the <em>individual substance</em> used in an FCM</em></td>
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<td><em>The current EU assessment and authorisation process is effective in ensuring the safety of the <em>final FCM</em></em></td>
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<td><em>The outcome and duration of the assessment and authorisation process supports innovation</em></td>
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<td><em>In the EU there is sufficient resources and expertise to adequately assess and authorise all substances used in FCMs in accordance with Articles 8 – 12 in a reasonable timeframe</em></td>
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<td>*The assessment of substances is sufficiently prioritised on the basis of the inherent hazard of the substances, including substances that are carcinogenic, mutagenic, reprotoxic (CMR) or endocrine disrupters</td>
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<td>*The assessment of substances is sufficiently prioritised on the basis of the use and/ or presence of the substances and potential exposure</td>
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<td>*The exclusion and / or derogation of certain substances from authorised list of substances e.g. colourants, is justified and sufficiently controlled at national level</td>
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<td>*The review and prioritisation of the risk assessment and risk management of substances on the authorised list is sufficient</td>
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<td>*Assessment and availability of analytical methods for control purposes of authorised substances is sufficient</td>
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<td>*The safety of substances in FCMs can only be ensured if the intended use of the final material is known at the time of their assessment</td>
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<td>*Rules supporting authorised lists of substances to ensure compliance are simple to understand and comply with and enforce in practice</td>
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<td>*Assessment and demonstration of compliance of substances not in the authorised list, such as non-intentionally added substances (NIAS) is effective</td>
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<td>*The safety of all substances should be assessed by public authorities, business operators have no role in this</td>
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*Concerning Article 18 of Regulation 1935/2004, is the use of temporary national rules on the basis of urgent health-related concerns justified?*

- Yes
- No
- No opinion

*How many consumer complaints on FCM do you receive approximately every year?*

50 character(s) maximum

none, as we are NGO

*What do most consumer complaints on FCM concern?*

400 character(s) maximum

-
The purpose of the FCM legislation is to ensure that FCMs are manufactured so that they do not release their constituents into food in quantities that endanger human health under normal or foreseeable conditions of use. Is this objective still relevant?
- To a large extent
- To a moderate extent
- To some extent
- To a small extent
- Not at all
- Don't know

The purpose of the FCM legislation is also to ensure FCMs can be marketed throughout the EU without hindrance. Is this objective still relevant?
- To a large extent
- To a moderate extent
- To some extent
- To a small extent
- Not at all
- Don't know

To what extent do you consider that the FCM legislation stimulates or allows for innovation and research?
- To a large extent
- To a moderate extent
- To some extent
- To a small extent
- Not at all
- Don't know

Does the FCM legislation appropriately reflect all the latest technological, scientific and social developments?
- To a large extent
- To a moderate extent
- To some extent
- To a small extent
- Not at all
- Don't know

Are you aware of any contradictions, gaps, overlaps, inconsistencies or missing links within the EU FCM legislation?
- Yes
- No
- Don't know
- No opinion

If 'yes', please give details
400 character(s) maximum
Harmonised rules for all FCM are needed. No unassessed chemicals in final articles should be accepted. Risk assessment must include other sources of exposure, and more focus is needed on protecting consumers against EDCs and non-threshold chemicals in general. See the five new key principles for the future food contact legislation https://chemtrust.org/5-key-principles-fcm/

*Are you are aware of any contradictions, gaps, overlaps, inconsistencies or missing links between the EU FCM legislation and other EU legislation, in particular on chemical safety or products? This may include other areas, which you consider should be legislated together with FCM in the same legislation or legislative framework?

- Yes
- No
- Don't know
- No opinion

If 'yes', please give details

*New data, new classification, SVHC identification and restriction under REACH and other legislation must lead to immediate and adequate restrictions in FCM. Focus should be on EDCs, DNTs and other substances of high concern. The exemptions in REACH article 14,5 and 56, 5b are not warranted as long as no similar safety provisions for FCM are in place*

*Is it better to have specific FCM rules which are applicable throughout the EU, or to have individual Member State legislation?

- It is better to have EU legislation
- It is better to have individual Member State legislation
- Don't know
- No opinion

To what extent do you agree with the following statements concerning the EU added value of Regulation (EC) No 1935/2004 and its implementing acts?

5 = strongly agree; 4 moderately agree; 3 neither agree nor disagree; 2 moderately disagree; 1 = strongly disagree.

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<td><em>It ensures the same level of health protection for all EU consumers</em></td>
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<td><em>It creates a level playing field for all FCM businesses</em></td>
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<td><em>It helps facilitate market surveillance across Member States.</em></td>
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<td><em>It helps harmonise testing methodologies and standards.</em></td>
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<td><em>It lowers manufacturing and compliance costs</em></td>
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Document upload and final comments

Please feel free to upload a concise document, such as a position paper. The maximum file size is 1 MB. The uploaded document will be published alongside your response to the questionnaire which is the essential input to this public consultation. The document is optional and serves as additional background reading to better understand your position.

Please upload your file
The maximum file size is 1 MB
Only files of the type .pdf,.txt,.doc,.docx,.odt,.rtf are allowed

If you wish to add further information — within the scope of this questionnaire, to substantiate or exemplify any of your answers — please feel free to do so here

750 character(s) maximum

The new legislation should be based on the 5 new key principles developed by a group of NGOs and published in April 2019: https://chemtrust.org/5-key-principles-fcm/

Contact
SANTE-FCM-EVALUATION@ec.europa.eu