

## 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 consultation process by which the Commission intends to establish the 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 the possible solutions the Commission intends to assess. Only during the subsequent consultation, any relevant information that they may have should be made available, including on possible impacts of the different options.

<b>TITLE OF THE INITIATIVE</b>	Migration limits for lead, cadmium and possibly other metals from ceramic and vitreous food contact materials
<b>LEAD DG (RESPONSIBLE UNIT)</b>	DG Health and Food Safety – Unit E2 (Food processing technologies and novel foods)
<b>LIKELY TYPE OF INITIATIVE</b>	Regulatory Procedure with Scrutiny
<b>INDICATIVE PLANNING</b>	Q3 2020
<b>ADDITIONAL INFORMATION</b>	Please see <a href="#">Food Contact Material consultation page</a> . (under 'Ceramics')

**This Inception Impact Assessment is provided for information purposes only. It does not prejudice the final decision of the Commission on whether this initiative will be pursued, on the actual consultation process, or on its final content. All elements of the initiative this Inception impact assessment describes, including its timing, are subject to change.**

### A. Context, Problem definition and Subsidiarity Check

#### Context

The European Commission aims to ensure a high level of food safety for consumers. The implementation of the EU's [integrated Food Safety policy](#) is based on solid science and thorough risk assessment and, among others, protects consumers from exposure to hazardous chemicals.

Food contact materials (FCMs) are materials such as plastics, paper, ceramics, glass, metals and alloys that are widely used in everyday life in the form of food packaging, kitchen and tableware, appliances and processing equipment. The chemical constituents of these materials may transfer into food, bringing changes in food safety and quality. In this context, [EU legislation on FCM](#) provides that these materials [shall neither adversely affect consumer health nor influence the quality of the food](#), and [shall be manufactured under good manufacturing practices](#). The legislation also empowers the Commission to establish limits on the migration of chemicals from FCM into food.

Kitchen and tableware manufactured from ceramic and vitreous<sup>1</sup> materials widely circulate in the internal market, and are often imported. Their manufacture may involve specific metal oxides that are added to obtain desired properties, and for which alternatives are limited. Industry uses lead, barium and aluminium primarily for technical purposes. Lead oxide facilitates processing and appearance; it is used in particular at high percentages in glazing and crystal to lower the melting point. The use of lead oxide is also considered a quality requirement for glass which is protected by EU legislation ([Council Directive 69/493/EEC](#), 'the crystal Directive') requires that glass can only be named 'lead crystal' when it contains at least 24% of lead oxide). Many other metal oxides are used as colorants for decoration purposes. These oxides are often used in artisanal and traditional techniques to manufacture products that may have a special regional or local cultural value<sup>2</sup>.

Many metals, particularly heavy metals, are known to be dangerous to human health. In recent decades, in response to a growing awareness of the need to control exposure, there has been increasing emphasis on establishing appropriate regulatory measures to control the use of heavy metals in general. Many are considered substances of very high concern under REACH<sup>3</sup>. Lead and its compounds have specifically been restricted in petrol, electrical goods, jewellery, and in consumer articles, and maximum levels in drinking water and food have

<sup>1</sup> 'vitreous materials' include glass and glass enamels

<sup>2</sup> The mentioned metals may also intentionally be used by producers of mainstream tableware in their production processes but either in smaller amounts or on the outside or may be present as impurities.

<sup>3</sup> [https://ec.europa.eu/growth/sectors/chemicals/reach\\_en](https://ec.europa.eu/growth/sectors/chemicals/reach_en) Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals.

been specified. As a result, the overall exposure to metals decreased significantly over recent decades, but in 2013 it was found to have reached a steady state at a level still toxicologically relevant.<sup>4</sup>

With respect to food contact materials, since 1984, [Directive 84/500/EEC](#) ("the Directive") sets out limits for lead and cadmium transfer from ceramics in order to protect human health. However, in 2009 and 2010 the European Food Safety Authority (EFSA) published new scientific advice on the health effects of [lead](#)<sup>5</sup> and [cadmium](#)<sup>6</sup> in food. EFSA concluded that exposure to lead can cause negative health effects at any dose and significantly lowered its recommendations for what constitutes a tolerable intake level for cadmium. The observed health effects of lead include developmental neurotoxicity (lower Intelligence Quotient) in developing children, for whom there is no safe exposure level, as well as cardiovascular effects and neurotoxicity in adults. Cadmium exerts toxic effects after long-term exposure on the kidney and bones. EFSA concluded that exposure to lead and cadmium should be significantly reduced, and noted that dietary exposure is the main source of exposure to these heavy metals.

In the light of the new scientific evidence from EFSA, some Member States noted that the existing migration limits for lead and cadmium in the Directive would not provide a sufficient protection of exposure for consumers. Hence, they have requested the Commission to lower them to safe levels in light of the new scientific evidence. The glass and enamel industry furthermore pointed at the need to establish similar legislation for these materials, as their products would in practice already be regulated based on the limits set out in the Directive.

Moreover, similar scientific evidence has become available for the toxicity of several other metals<sup>7</sup>. This makes clear that these metals also migrate from ceramic and vitreous materials in amounts that are potentially hazardous to health. These metals include for instance aluminium, arsenic, barium, cobalt, chromium and nickel. Chromium, in its hexavalent form (CrVI), is considered to be carcinogenic. Other metals with toxic properties, such as arsenic and mercury, may be present as impurities. Some Member States already impose limits on metals other than lead and cadmium (see [annex 12 and 13 of the study](#) carried out by the Commission's Joint Research Centre (JRC) on non-harmonised food contact materials).

Earlier consultations with Member States in 2012 identified knowledge gaps on the actual migration of metals from ceramics and vitreous materials into food as well as on available testing methods required for verification of compliance. In order to address these gaps, the JRC conducted [research](#)<sup>8</sup> on the topic, testing approximately 6000 samples provided by industry. This work concluded in 2017 when the JRC noted that [robust analytical methods](#) exist<sup>9</sup> and that these are representative for food use.

Data received from the official controls done by some Member States indicate that, for approx. 20% of the tested ceramic and vitreous samples, heavy metals migrate into food at amounts that would cause adverse health effects in view of the new scientific evidence. This data also shows that particularly artisanal and traditional products are concerned, and their products show a higher than average migration of heavy metals into food.

### **Problem the initiative aims to tackle**

Potentially toxic metals are used in ceramic and vitreous materials for technical purposes (mainly lead, barium and cadmium), and as decorative pigments (cadmium and several other heavy metals). Directive 84/500/EEC sets out limits only for lead and cadmium in ceramic materials but not for vitreous materials, for which no harmonised legislation exists.

EFSA published opinions on the adverse health effects of lead and cadmium, as well as on other metals. For lead and cadmium, these show that the adverse effects occur well below levels currently set out in the Directive. The JRC study and enforcement data confirm that these heavy metals indeed migrate from a significant number of ceramic and vitreous FCMs in toxicologically relevant amounts. The expected consumption patterns of food in contact with these materials would lead to intake amounts that may adversely affect health in light of the latest science-based risk assessments. Furthermore, some Member States have adopted legislation to impose limits on certain metals at national level.

These matters need to be addressed, to ensure an equal and adequate level of health protection across the EU, and a level playing field for operators in the internal market.

<sup>4</sup> [ECHA/RAC/RES-O-0000003487-67-04/F](#), Opinion of the Committee for Risk Assessment on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU, lead and its compounds, 12/2013.

<sup>5</sup> [Scientific Opinion on Lead in Food](#). EFSA Panel on Contaminants in the Food Chain (CONTAM) First published: 20 April 2010 (updated 22 March 2013)

<sup>6</sup> [Cadmium in food](#) - Scientific opinion of the Panel on Contaminants in the Food Chain First published: 20 March 2009

<sup>7</sup> Examples include: Aluminium, EFSA Journal (2008) 754, 1-34; Chromium EFSA Journal (2009) 980 and EFSA Journal (2014) 3595; Cobalt, EFSA Journal (2012) 2791; Nickel, EFSA Journal (2015) 4002

<sup>8</sup> Towards suitable tests for the migration of metals from ceramic and crystal tableware: Work in support of the revision of the Ceramic Directive 84/500/EEC Joint Research Centre (European Commission) 2017

<sup>9</sup> Report on the inter-laboratory comparison exercise organised by the European Union Reference Laboratory for Food Contact Materials Joint Research Centre (European Commission) 2017

<b>Basis for EU intervention (legal basis and subsidiarity check)</b>
<p>Regulation (EC) No 1935/2004 provides a harmonised EU legal framework for FCM in order to promote the functioning of the internal market and the free movement of goods. A harmonised approach avoids an inflation of national approaches leading to a real risk of market fragmentation. The Regulation sets out the general principles of safety and inertness for all FCMs and provides the basis for setting out specific measures, to be adopted through the regulatory procedure with scrutiny, on specific materials (including ceramic and glass materials, as well as coatings that in turn include enamel applied on metal or ceramic materials). In particular, Article 5(e) therefrom empowers the Commission to set limits on the migration of Food Contact Materials constituents into food, taking due account of other possible sources of exposure to those constituents.</p> <p>In this context, Directive 84/500/EEC already regulates ceramic food contact materials by fixing harmonised limits to the migration of lead and cadmium into or on to the surface of food<sup>10</sup>. For those heavy metals where no harmonised rules exist, some Member States have introduced diverging safety requirements for FCM's, including migration limits that affect the manufacturing and sale of those products. These divergent requirements in the Member States could adversely impact on their free movement in the single market.</p>
<b>B. Objectives and Policy options</b>
<p>The general objectives of the initiative are to protect human health and contribute to the smooth functioning of the single market.</p> <p>The specific objectives are:</p> <ul style="list-style-type: none"> <li>- To protect human health by ensuring that exposure to metals migrating from ceramic and vitreous food contact materials is consistent with the latest science-based risk assessments;</li> <li>- To enhance legal certainty for manufacturers of ceramic and vitreous food contact materials;</li> <li>- To minimise potential adverse impacts on traditional and artisanal production and culturally valuable products.</li> </ul> <p>The following options will be considered:</p> <ol style="list-style-type: none"> <li>1) Do nothing: the present measure with the current limits for lead and cadmium will continue to apply to ceramics. No EU limit will apply to vitreous FCM and no EU limit would be set for other heavy metals.</li> <li>2) Establish appropriate protective migration limits for lead, cadmium and possibly other heavy metals, in ceramic and vitreous food contact materials. Where no protective migration limits could be set, the possibility of bans on certain metals for certain uses will also be considered.</li> </ol> <p>However, different provisions to mitigate the possible negative impacts for manufacturers would accompany option 2. These will be developed and assessed as partially dependent building blocks during the impact assessment, with the aim to minimise the total impact on business operators of the limits that need considering for health reasons. Presently foreseen blocks would potentially include derogations for traditional and artisanal production; measures aimed at facilitating quality control throughout the supply chain, including labelling, documentation, quality control, manufacturing instructions, and resulting testing exemptions; longer transition periods in case of specific needs requiring major investments.</p> <p>Option 2 would also include provisions to guarantee compliance with composition and manufacturing requirements along the production chain, traceability requirements of materials and goods, and provisions aimed at reducing testing requirements. To this purpose, adding an annex specific to Regulation (EC) No 2023/2006 on Good Manufacturing Practices will be considered. Where relevant, the assessment will consider the pigments separately from the group of metals used for technical reasons.</p>
<b>C. Preliminary Assessment of Expected Impacts</b>
<b>Likely economic impacts</b>
<p>The options will be assessed against the baseline, which is the present situation (Option 1), i.e. the level of protection provided by the current legislation as regards ceramics, and for vitreous materials the situation as described in the JRC report on <a href="#">non-harmonised materials</a>.</p>

<sup>10</sup> Directive 84/500 implements Council Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs ([OJ L 340, 9.12.1976, p. 19](#)), with the objective of preventing differences between national laws becoming an impediment to the free circulation of such products, or creating unequal conditions of competition and thus affecting the functioning of the single market. Council Directive 76/893/EEC is now replaced by Regulation 1935/2004.

<p>Previous stocktaking discussions with the Member States and industry confirmed the potential significant burden of substantial lowering or introduction of new limits to heavy metals for certain business operators, in particular traditional and artisanal producers, which are mostly small and micro enterprises. While about 20% of all products would not be compliant to these new limits, those non-compliant products would mostly originate from these small producers. For these producers it appears difficult to apply more modern production techniques, as the value of their products derives directly from the use of traditional techniques. Also the relative cost for testing of small artisanal batches would likely represent a significant additional burden.</p> <p>This will be analysed in the impact assessment, including by reviewing the consequences of similar measures implemented in other jurisdictions. If limits are established, all manufacturers of ceramics and vitreous materials may be required to test, even if they would not intentionally use a regulated heavy metal. In particular mainstream producers that do not intentionally use heavy metals, report potential high compliance costs because of testing requirements and the need to avoid impurities. Ensuring a sufficient and harmonised level of controls, including at import, may cause further economic burden to EU producers, while such controls would represent an increased investment by the Competent Authorities.</p> <p>The harmonising effects of the different options should result in positive aspects, in particular for the manufacturers of vitreous materials because they would ensure an equal playing field in the European Union. Consequences for consumers (e.g. in terms of prices and/or product variety/availability) and employment in the affected sectors will be considered as well.</p>
<p><b>Likely social impacts</b></p> <p>The impact assessment will assess the overall health benefits of this measure by reducing consumer exposure to heavy metals. Occupational health and safety will likely be positively affected, as a consequence of a lower use of the involved metals.</p> <p>In the absence of adequate mitigation measures, a negative impact on traditional and artisanal products is expected, leading to extra costs for manufacturers to adapt, and to increased unemployment in specific regions or cities. This might also have a negative impact on the cultural diversity of the European Union.</p>
<p><b>Likely environmental impacts</b></p> <p>The initiative will likely reduce the use of heavy metal in production processes, resulting in a (indirect) positive environmental impact.</p>
<p><b>Likely impacts on fundamental rights</b></p> <p>Not applicable</p>
<p><b>Likely impacts on simplification and/or administrative burden</b></p> <p>Given the simplicity of the current Directive, an increase of complexity is likely. The introduction of new limits, and particularly any additional provisions aimed at minimising the burden that new or lower limits may cause, is expected to increase complexity. The work for the Competent Authorities may also become more complex as they may have to deal with more complex control of imports. Also at the start of the implementation of the new regulatory requirements, other enforcement actions (training of control staff, new testing requirements) will have to be undertaken.</p>
<p><b>D. Evidence Base, Data collection and Better Regulation Instruments</b></p>
<p><b>Impact assessment</b></p> <p>A proportionate impact assessment is being prepared to support the development of this initiative and to inform the Commission's decision.</p>
<p><b>Evidence base and data collection</b></p> <p>A significant evidence base exists already. EFSA opinions on lead, cadmium and other heavy metals, as well as work from the JRC will be the scientific foundation for this impact assessment. The data on market controls received from some Member States provide a consistent estimate of the number of affected products. On <a href="#">lead, a report</a> by the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency is available, which estimates the economic damage of lead intake.</p> <p>The JRC studies will help to shape the perspective on costs of compliance testing. With the limits and the analytical approach clarified, further evidence on economic and social impacts need to be gathered to verify the impact, particularly on traditional and artisanal producers. Still missing is also clear information on the additional administrative burden for the competent authorities. This data will be gathered primarily with targeted questionnaires and interviews with the relevant stakeholders.</p>
<p><b>Consultation of citizens and stakeholders</b></p> <p>The Commission services already started the consultations with stakeholders and Member States on lowering the limits in 2012, which included targeted consultations, specific meetings and an SME panel consultation. Consultation activities will aim at substantiating the magnitude of the problem, assessing the feasibility of the</p>

different options and identifying the size and distribution of their likely impacts.

The consultation approach will consist of two major elements:

- A 12-week open public consultation. The questionnaire will be available in all 24 official EU languages and will be accessible via the Commission's central [public consultations page](#) and via the [FCM consultation page](#).
- Targeted questions will be sent to representatives of the Member States and specific stakeholder groups. Those not represented yet can register via the [FCM consultation page](#).

Specific efforts, in particular via the Member States, will be made to reach out to traditional and artisanal producers and their supply chain, as far as possible in all required official EU languages, in order to ensure their awareness and full consultation. A further SME panel may be considered depending on the outcome of these consultations.

The synopsis report on all consultations carried out will be published on the consultation page once all consultation activities are finalised.

**Will an Implementation plan be established?**

Not applicable