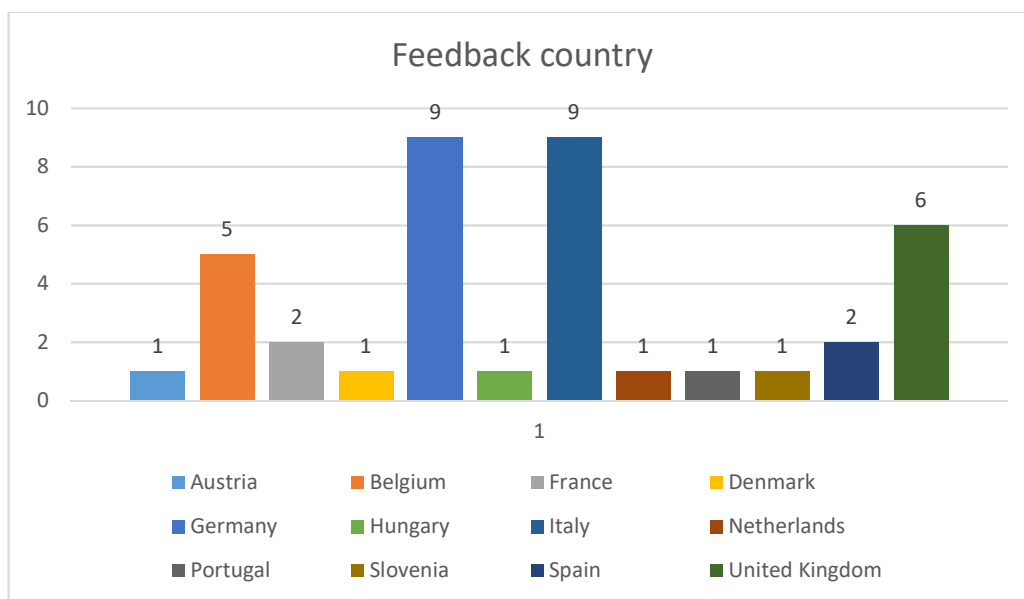


IIA Feedback summary and discussion

1. General information

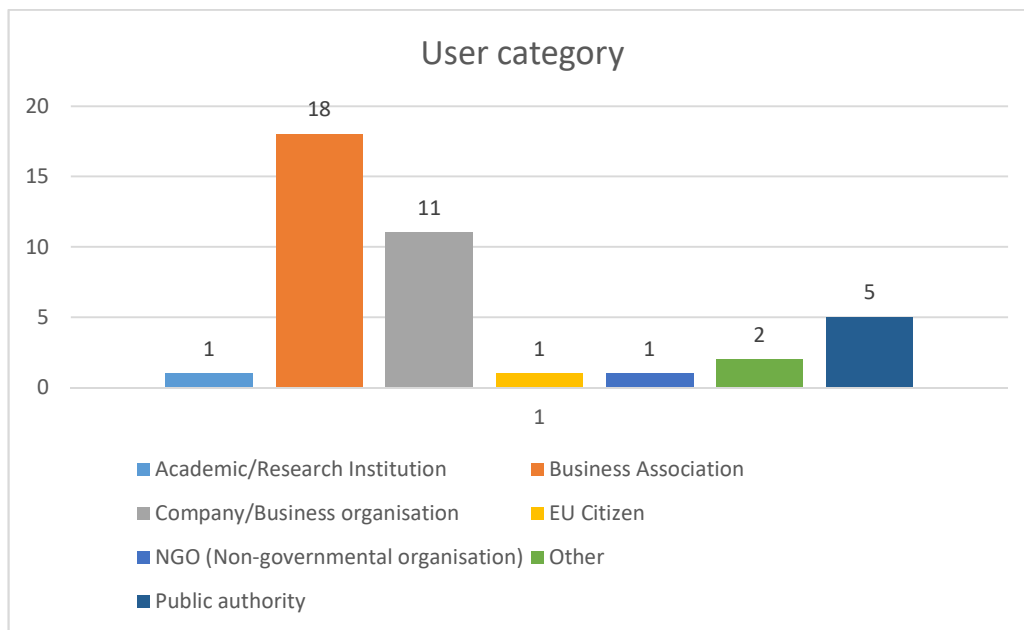
Following the publication of the Inception Impact Assessment (IIA) on new migration limits for lead, cadmium and other metals from ceramic and vitreous food contact materials (FCM), 39 stakeholders responses were collected during the feedback period between May 21 and June 26 2019. Feedback come from 12 different European countries, with Italy and Germany being the two most represented ones (Figure 1).

Figure 1



Concerning the type of organisation, the vast majority of the responses were delivered by individual companies or business association representing the industry. 5 public authorities from Italy, Netherlands, Denmark, Belgium and UK provided their feedback to the IIA. The remaining responses were provided by EU citizens, NGO or other private organisations (Figure 2).

Figure 2



The scope and content of the feedback highly depends on the type of the organization and therefore, for the sake of comprehension, the following document is structured with different sections containing feedback from users of the same category and industry.

2. Feedback from stakeholder

2.1. Feedback from public authorities

Overall, public authorities agree that the limits for different metals on FCM must be lowered based on the recent scientific news. In setting the policy objectives, the Dutch Ministry of Health and Belgian Federal Public Service Health recommend that public health interest should prevail over other private interests and the Danish Veterinary and Food Administration does not agree on specifying “the mitigation option” as an objective, arguing that its importance cannot be equated to the protection of human health.

Some public authorities express concerns regarding the proposed solution of applying a two-tiered approach for artisanal and traditional manufactures, arguing that it would potentially harm consumers and increase the burden on Competent Authorities. The Italian Minister of health and British food agency calls for a discussion on the definition of traditional and artisanal producer to avoid misclassification and incorrect applications among different Member States.

The use for labels is considered potentially harmful for tourists (if the label is made in the language of the country of origins) or to consumers ignoring them. Italian health minister recommends developing distinct strategy and limits according to each material considered in the regulation (ceramics, glass,

enameled glass). Finally, Dutch Ministry of health offers its own legislation on the matter as a starting position for discussion.

2.2. Feedback from ceramic industry

The ceramic industry highlights the need of clearly defining the limit values and the scope of the legislation. Clarity in the regulation is required also regarding the differences between substances naturally occurring or artificially added and the science supporting the decision to limit metal species.

Testing is considered potentially problematic. The standard test recommended to detect low quantity of metals, ICP-MS, is apparently not widely available and potentially expensive.

Moreover, some businesses express their concerns that the level proposed are hardly achievable for many artisanal manufactures and special provision for traditional or artisanal producers alongside an adequate transition time are considered necessary.

Given the potential impact on employment in some European regions where ceramics artisans represent a large share of income, the ceramics industry calls for an appropriate evaluation of the social consequences of the regulation. Different limit values should also be considered in the impact assessment.

Finally, the use of the implementing act was mentioned to be inappropriate for a regulation that should try to involve stakeholders as much as possible.

2.3. Feedback from glass industry

The glass industry agree that a harmonized legislation for FCM at the European level is desirable although they favour a pragmatic approach on limits and testing. In particular, industry representatives argue that mainstream soda-lime glass has been demonstrated to be safe for FCM and should be exempted from systematic testing. Other kind of glass materials, differently from ceramics, come from homogenous materials, therefore no more testing should be needed if an article coming from a material batch has proved to be safe. Moreover, it was proposed to exempt from testing articles that maintain a non-decorated area of 2 cm from drinking rim.

Considered that not all glass industry is intended for FCM, a ban on metals may affect overall glass market. A full assessment instead of a proportionate one would be preferred, with limit values based on testing methods and real usages. Finally, glass industry calls for a better enforcement of European regulation on imported goods.

2.4. Feedback from enamel and ceramic colorants industry

The enamel industry raises concerns that, at the new limits, almost 50% of the colours would be withdrawn from the market as alternatives for ceramic colours are often not available now. That would have a severe impact on onglaze colours and glaze sector in general. The impact caused by the increased cost of test methods is also mentioned as potentially burdensome.

Nevertheless, the industry recognizes that a harmonic regulation on the matter is needed to avoid uncoordinated national initiatives damaging the single market.

The Austrian Enamel association recommends implementing the standard regulation EN ISO 4351 instead of proposing new ones.

2.5. Feedback from other stakeholders

An ongoing survey by the Slovenian delegation of the Council of Europe Committee suggests that a certain proportion of vitreous enamels exceed the limit values, specifically for cobalt and lithium.

Other consumer associations express the need to protect public health and to improve the harmonization of FCM regulation taking into account consumers' behaviours and scientific data.

3. Discussion

Overall, ceramic colorants and enamel industry appears to be the most concerned, claiming that the new limits risk to significantly harm the industry. The ceramic industry seems concerned mostly for the potential impact on artisanal producers and the availability of testing facilities. The glass industry, instead, seems confident that most of their articles already comply with the new limits and raises concerns regarding the potential burden of systematic test. Public authorities stress the importance of setting public health as a priority objective and are concerned mostly on the potential burden on Competent Authorities caused by a complex regulation with different limits and derogations.

As stressed by the Danish Veterinary and Food Administration and given the different scopes and conflicting nature of the objectives specified in the IIA, it might be appropriate to assess different policy scenarios:

- 1) Do nothing
- 2) Establish health based migration for lead, cadmium and other metals for ceramic, enamelled articles and glass (primary objective: public health)
- 3) Establish health based migration limit with provisions to mitigate negative impacts for artisanal and traditional producers (primary objectives: public health and impact mitigation)

While comparing the scenario 2 with scenario 1 would tell us the full economic and public health impact of the policy, comparing scenario 3 and 2 may be necessary to understand the effectiveness of the mitigation measures adopted.

The feedback highlights the need to collect more information and data to effectively conduct an IA. Firstly, regarding the compliance cost, actual testing cost is unknown as it is not clear whether enough laboratories equipped with ICP-MS technology are available. It is likely that a major consequence of the policy would be the reduction of recognised testing facilities (using AA technique) and this may have a significant impact on the production. The number of tests required is also unknown. Whereas for ceramic objects a testing rate of 0.1 - 1% may be appropriate (within the framework of US consumer Safety Improvement Act), testing requirement may be lower for homogenous glass products or for producers adopting certified "safe" materials and technique. As testing cost would be the only compliance cost for most of the producers, it is important to acquire enough information during the next consultancy in order to be able to properly estimate the cost.

More information is needed on the availability and cost of alternative materials and production techniques for the non-compliers, most of them being likely traditional or artisanal producers, and on

the time needed to adapt to the new regulation. Likewise, the definition of artisanal or traditional producers should be clear and widely accepted in order to avoid divergences across member states.

Several mitigation measures proposed would likely increase the administrative burden and cost of producers and Competent Authorities alike, as the latter will be required to enforce different limit values according to the type of manufacture. The European Commission has adopted a standard cost model for estimating administrative costs but it may be important to acquire information during the consultation regarding the increased administrative burden predicted by public authorities.

Finally, the efficacy of labels in preventing misuse of articles and their potential effect on demand need to be assessed. It has been mentioned that most of the kitchenware non-complying with the new limits, consists in expensive wares not used or used only occasional as a FCM. If this is the case, implementing new labels should only slightly affecting sales. However, it is not clear whether labels would be as effective as implementing new limits in reducing exposition to hazardous metals.