Verband der Mineralfarben-industrie e. V.

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VdMi position on the EU initiative to lower migration limits for lead and cadmium and to set new migration limits for other metals from ceramic and vitreous food contact materials

In spring 2021, the EU Commission launched a study to support the impact assessment of the initiative to introduce migration limits for lead, cadmium, and possible other metals from ceramic and vitreous materials for food contact (consumer goods).

The VdMi sector department EGK (Ceramic Colours) as well as the European association Eurocolour e. V. participated in the study by taking part in an interview - based on a questionnaire sent out beforehand.

The aim of the study is to assess the impact of lowering the migration limits for lead and cadmium in ceramic materials compared to today (especially for traditional ceramic products / handicraft products) and the introduction of migration limits for other elements (aluminium, arsenic, barium, cobalt, chromium and nickel) in ceramic food contact materials (FCM) for the industry concerned. This includes assessing the impact of the proposed mitigation measures and the extension to vitreous food contact materials.

The previous legislative initiative of the EU Commission proposes a significant reduction of the migration limits for cadmium and lead (compared to the previously valid SML values in the Ceramics Directive 84/500/EEC) as well as the introduction of new migration limits for other metals (aluminium, arsenic, barium, cobalt, chromium and nickel) in ceramic and vitreous food contact materials.

Brief summary and evaluation:

- The EU Commission's proposals will have significant consequences for ceramic precursors such as ceramic colours and frits as well as glazes, and in particular onglaze colours.
- Due to the very low limit values, a large number of precursors will no longer be applicable as before, which will have a considerable influence on the variety of colours and the type of decoration of consumer goods (especially tableware).
- Ceramic colours require special technical properties for their use on tableware; the most important of these is mechanical resistance and fusion with the glaze. This can only be achieved with inorganic flux and pigments, which is why an exchange of ceramic precursors is only partially possible; there are hardly any alternatives of equal value available.
- A sufficient colour spectrum is also necessary for decorative applications, which includes at least all intensive primary colours (black, red, green, blue).
- The very low limit values are likely to require high investments in new analytics by the manufacturers of ceramic food contact materials and their suppliers; the previous standard analytics (e. g. ICP-OES) will not be sufficient, instead a considerably more time- and cost-intensive analytics by means of ICP-MS will be necessary.

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Detailed evaluation of the EU Commission's proposals on migration limits for metals from ceramic and vitreous consumer goods

The first plans of the EU Commission to revise the Ceramics Directive 84/500/EEC became known as early as 2012. These initially envisaged lowering the limit values for lead by a factor of 400 to 10 µg/l and for cadmium by a factor of 60 to 5 µg/l. With the current proposal, the limit value for cadmium has been further lowered to 2 µg/l. The justification given is that the limit values are based on EFSA risk assessment methods, which derive the proposed limit values based on health; specifically, the SML (in g/kg food) of the metals for Food Contact Materials is derived from the weekly or daily intake limits of the metals. This means that the proposed SML values for the metals have no relation to the current analytical detection limit, i.e. the current state of available analytics. In practice, the reductions in limit values for lead and cadmium derived in this way, and the newly introduced limit values for the other metals, pose major analytical and technical challenges for our industry/the companies and will have considerable economic consequences.

The intention to introduce migration limits for further elements had already been known for some time; the present draft now concretises the proposals for migration limits for the elements aluminium (1000 µg/l), arsenic (2 µg/l), barium (1200 µg/l), cobalt (20 µg/l), nickel (20 µg/l) and chromium (chromium(III) (3600 µg/l) and chromium (VI).

The proposed limit values are partly lower than the limit values in baby food and drinking water: According to Regulation (EU) 1881/2006 setting maximum levels for certain contaminants in foodstuffs and its amendments, the maximum permitted level of lead in baby food, for example, is set at 0.02 mg/kg; however, the proposed SML for lead from ceramic and vitreous FCMs, is 0.01 mg/kg = 10 µg/kg. The general intake of these elements via tableware and the like is much lower and should be negligible compared to the intake from the food itself, as shown by the average cadmium content of foods with higher levels such as sunflower seeds (0.39 mg/kg).[1]

Numerous ceramic precursors affected – few technically adequate alternatives

Basically, it can be said that the introduction of the limit values/SMLs for the above-mentioned elements affects almost all precursors of ceramic consumer goods, such as ceramic decorative colours and frits as well as glazes, and in particular onglazes and onglaze colours.

Ceramic colours must have certain properties for their use on tableware. An important quality is mechanical resistance and good adhesion to the inorganic glaze. Therefore, it is often not possible to replace the essentially inorganic starting materials with technically comparable alternatives, as is possible in other fields of application (e. g. coatings or plastics). In addition to the purely technical properties, the colour impression is also essential for the application as a decorative paint. The proposed limit values would considerably reduce the variety of colours, as several of the named elements play an essential role in the colouring of inorganic materials; cadmium for red-orange tones, chromium for intense green, nickel for intense black and cobalt for blue. Without the use of these metals in the onglaze application, the intensity and colour spectrum of the decoration would be considerably limited.

Especially in the field of traditional ceramic handicraft products, many lead-containing glazes and onglaze colours are still in use. Since lead-containing colours are characterised by an exceptional tolerance towards variable layer thicknesses, there is no substitute for these colours.

If a distinction is made between hollowware (e. g. cups) and flatware (e. g. plates), the required migration limit values and the resulting consequences have the greatest influence on flatware (plates), since here large areas are decorated and not just the rim or the outside (as is the case with a cup, for example).

[1] Cadmium in food - BfR (bund.de)

Low SML values require high analytical effort

Due to the very low limit values resulting from the health-based derivation, it is to be expected that the analytical method ICP-OES currently used in our industry will not be sufficient; instead, analysis using ICP-MS, which is considerably more time- and cost-intensive, will be necessary.

As a test method, the JRC has already developed a test procedure, which is intended to enable the determination and thus the verification of compliance with the low limit values on the food contact material; this involves triple elution with 4% acetic acid at 22 °C, 24 h (so-called leaching method, 3rd wash). [2]

Extension of the EU initiative to vitreous FCMs rather of minor relevance

Unlike tableware, glasses are often only decorated with glass colours on the outside. Most glass colours are not suitable for direct food contact. Glass colours are essentially only used for the outside areas (e. g. on glasses), and the rim of the glass is not coloured either. Thus, there is no direct contact with the food and no migration takes place through the glass barrier. The relevance of the extension of the regulation to vitreous food contact materials is therefore considered to be low.

Question of EU imports unresolved - goal of the regulatory measure clearly missed

The proposed limit values would be a considerable competitive disadvantage for consumer goods produced in the EU. and in particular their precursors, i.e. glazes and ceramic decorative colours. This could lead to a complete relocation of the relevant industries from Europe. The consistent control of EU imports for compliance with the regulation is questionable, as the tests are time-consuming and costly and have to be carried out individually for each decor design. Thus, the actual objectives of regulation, namely the protection of human health on the one hand and the functioning of the market on the other, will not be achieved.

In the field of traditional ceramic handicraft products in particular, lead-based paints are used and there is no substitute for these paints. The consequence for these products would be that - without an exemption - they would no longer be allowed to be manufactured in the EU.

VdMi analysis to assess compliance with the new migration limits for metals from ceramic and vitreous FCMs

In order to assess the concrete effects of the newly proposed SML values for the other metals for the products of our industry sector (ceramic decorative colours, glazes), our members carried out migration tests on FCMs with selected ceramic colours and various glazes in a round robin test. It should be noted that these tests on the glazes or other precursors of the ceramic consumer goods do not release the manufacturer of the ceramic consumer goods from the obligation to carry out his own tests.

Tested materials and test conditions

Among others, the following ceramic precursors of ceramic consumer goods were examined:

- Glazes *(colourless silk matt as well as transparent glossy) on hollow vessels (cups)
- Glazes ** (matt as well as glossy, Ba-rich/poor, Al-rich/poor) on industrial cups
- Ceramic decorative colours *** (both for use in onglaze and inglaze, lead-free and lead-containing decorative colours)

Test conditions were according to the JRC method:

- Leaching with 4 % acetic acid at 22 °C, 24 h (so-called leaching method, in some cases as 3rd leaching, so called 3rd wash),

[2] https://publications.jrc.ec.europa.eu/repository/bitstream/JRC108092/final_report_ceramics_final.pdf

- * Analyses according to DIN 51302
- ** Analyses were carried out with the 1st leaching, so-called 1st wash
- ***The ceramic decor colours were tested with the JRC test method, 3rd wash with standardised décor size 10 cm x 10 cm in porcelain plates with a surface area of 268 cm^2 and a volume of 230 ml.[2]

Results and conclusions

The results and general conclusions from this round robin test/cooperative test can be summarised as follows:

- A significant decrease in permeability/migration from the first to the third immersion in acetic acid is observed for all elements examined. In particular, the decrease from the first to the second soak is significant. This supports the 3rd wash/triple elution test method recommended by the JRC.
- In the glazes on industrial cups that were specifically tested for the migration of aluminium and barium, the newly proposed limit values for aluminium (1000 µg/l) and barium (1200 µg/l) were met in all the glazes tested. The glazes (cups) were not tested for the presence of lead impurities as these were technically lead-free.
- For all glazes tested, i. e. both inglazes and onglazes, (both lead-free and lead-containing), the proposed limit values for aluminium, barium and nickel could be met.
- For the onglaze colours, the proposed limit values of Co, Cd and Pb could not be met.
- In the case of the inglazes, the limit values / permeability for all elements could be complied with, whereby investigations using ICP-MS were necessary for the elements lead and arsenic, since the sensitivity of the ICP-OES standard analysis is not sufficient and the proposed migration limit values for lead and arsenic are below the detection limit.
- With the proposed limit values, lead-containing glazes and lead-containing decorative colours will no longer be possible in the future, neither for onglaze nor inglaze application.
- It is to be expected that the suggested migration limit values can only be complied with in the future when using lead-free decorative paints in inglaze applications, with the associated restrictions in colour intensity.
- The permeability also essentially depends on the area of the decoration in comparison to the total area; thus, a decoration with ceramic decorative colours may still be possible if the area to be decorated is reduced. Thus, the reduction or introduction of the limit values can lead to the fact that certain large-area decorations will no longer be possible in the future, but in some cases smaller-area decorations with which the limit values on the finished article can then still be complied with. However, this requires complex migration tests and analyses that have to be carried out individually for each decor design.

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The Verband der Mineralfarbenindustrie e. V. represents German manufacturers of inorganic (e. g. titanium dioxide, iron oxides), organic and metallic pigments, fillers (e. g. silica), carbon black, ceramic and glass colours, food colorants, artists' and school paints, masterbatches and products for applied photocatalysis.