

ANNEX XV INVESTIGATION REPORT

Investigation into the state of the art of scientific information in terms of available analytical methodologies to determine migration of lead from the different materials used in consumer articles as well as the availability of alternatives to these materials and to certain articles exempted by paragraph 8 of entry 63 of Annex XVII of REACH to enable the Commission to conduct the required review of the restriction

SUBSTANCE NAME: Lead and its compounds

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Summary

The Commission has requested ECHA to prepare an evaluation report to assist the Commission with its review of the restriction on lead and its compounds in entry 63 of Annex XVII to REACH. Based on ECHA's report, the Commission will consider whether to request the Agency to prepare an Annex XV dossier in accordance with Article 69(1) to launch the procedure to amend the current restriction.

To enable the Commission to conduct the required review of the restriction, the Agency has:

1. Investigated the relevant analytical methodologies available to determine that the migration of lead from the different materials used in consumer articles does not exceed the limit of 0.05 mg/cm²/hour (0.05 µg/g per hour).
2. Assessed the suitability of wear test methods ensuring the coating integrity of articles for a period of at least two years of normal and reasonably foreseeable conditions of use.
3. Assessed the availability of alternatives or technologies that would advise the reconsideration of certain derogations from paragraph 8 of entry 63, including an assessment of the frequency and content of lead in these articles and the technical function provided by lead.
4. Made a quantitative assessment of the possible socio-economic consequences associated to potential removal of these derogations.

An assessment if the coatings mentioned in paragraph 7 of entry 63 are sufficient to ensure that the release rate of lead is not exceeded for a period of at least two years of normal and reasonably foreseeable conditions of use of the article could not be conducted in the time available for this report. However, it was considered that the first step in any review of this condition was to get confirmation of the appropriate test methods for migration of lead and the suitability of the wear test.

To support its assessment in the framework of the review of Entry 63, ECHA organised a call for evidence (CfE) (which lasted from 10/07/2019 to 26/09/2019) and a support contract with Eftec¹. This has provided a comprehensive feedback from many stakeholders affected by the possible lifting of the derogations. Some information has been submitted in the call for evidence as confidential and is therefore not part of the public report.

Suitability of test method EN 16711-3 for migration testing

EN 16711-3:2019 is a newly adopted European standard for the determination of lead release by artificial saliva solution, developed originally for textiles but, according to the experts consulted, applicable to all materials relevant in relation to Entry 63. However, the artificial saliva solution utilised in EN 16711-3 has not been optimised for lead migration testing. Although there are improvements possible to the existing testing method EN 16711-3, the further enhancements or the development of a new standard from scratch would be a resource consuming activity and should not be engaged in without a solid justification.

¹ Information gathering done in 2019.

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During the review ECHA was disclosed with migration testing reports by the industry, reporting unexpected migration values for brass items when tested with EN 16711-3. With approximately 3 % of lead, the anticipated migration level of lead for the article was expected to be over the migration limit but instead was actually below the detection limit. No difference between coated or non-coated items was found². Entry 63 of Annex XVII to REACH contains a derogation 8(g) for brass articles and parts of articles comprising brass alloys, if the concentration of lead (expressed as metal) in the brass alloy does not exceed 0,5 % by weight. The derogation was justified by RAC with studies showing that on average, migration of lead from brass containing items exceeds the limit of 0,05 µg/cm²/h when lead content is more than 0.5 % by weight. On the basis of the studies, anticipated migration level for brass item with lead concentration of 3 % would have been over 0.2 µg/cm²/h. According to experts consulted by ECHA, the inconsistency between the research-derived results and results from testing with EN 16711-3 by the industry may well rise from differences in the applied artificial saliva solution. Careful consideration for the possibility of false positives when applying EN 16711-3 should therefore be taken.

Furthermore, in line with a discussion within the framework of the Toys directive, it is clear the actual composition of the extraction liquid (artificial saliva) could be optimised further. Improvements to the testing method EN 16711-3 could lead to a further optimisation of the extraction saliva and that may give a better understanding of migration of lead from articles, and increase the effectiveness and efficiency of the method. This needs to be weighed, however, against some possible negative effects: increased complexity of testing and possible greater variation between tests. Any such improvement needs to be considered keeping in mind the purpose of the regulation the testing methods are required to support: offering an adequate level of protection of children against the harmful effects of lead in articles.

In the absence of information that would indicate that the current testing method is accurate enough and would avoid false positives, a benchmarking exercise comparing different compositions of artificial saliva could be performed. The purpose of such a benchmarking exercise would be to identify the optimal saliva composition for testing migration of lead, by comparing the current methods against other more elaborate methods. As brought up in the consultations, also the level of applied agitation and possible differences in materials may have an effect. Such a comparison would help to establish whether the current method (which has advantages in the laboratories in terms of simplicity, inert laboratory comparison and reproducibility) needs to be optimised further. The benchmark testing would need to establish whether trade-offs involved (less simple method) are worthwhile and could serve as input into deciding whether new test would need to be established.

To further clarify the possible issues of EN 16711-3 and feasibility of benchmark testing, ECHA received migration data from various consumer articles tested by TÜV Rheinland. Within the

² All articles are tested with EN 16711-3 for migration, regardless if coated or uncoated. Before EN 16711-3, coated items go through additional, simulated abrasion and wear test to clarify the coating integrity of those articles for a period of at least two years of normal and reasonably foreseeable conditions of use. The integrity itself is then tested after the abrasion and wear test with EN 16711-3 as the level of migration is higher if coating is eroded in the simulation. If the coating is durable the migration tested with EN 16711-3 should be low or same compared to non-coated items even after the wear test.

received dataset, highest migration of lead was recorded at near content limit (575 mg/kg of lead with migration of 1.9 µg/cm²/h) whereas values below detection limit were fairly abundant still at the highest contents (see Annex 4: The relationship of lead migration and content measured per EN 16711-3). Overall, no linearity could be detected between the content and the migration of lead in the tested articles. Therefore, it cannot be concluded on the basis of this limited data set that the aspect of artificial saliva solution only in EN 16711-3 would account for the discovered inconsistencies between anticipated and realised migration of lead in relation to content. However, this cannot be excluded either. Based on two expert opinions, linear relationship between lead content and migration has not been discovered in practice. Factors affecting the migration can include not only the applied saliva solution but also the characteristics of the article surface in terms of material and corrosion. The level of applied agitation should also be considered between different materials.

Suitability of the wear test method EN 12472

The suitability of the wear test method EN 12472:2005+A1:2009 was concluded to be satisfactory. The consulted experts were of the opinion that the test is well suited for this use and there has been much experience gained from its previous use in relation to nickel release testing. Variations on the level of corrosion may however rise if the contents of the abrasive paste is changed as it may facilitate polishing of the surface of the item. Similar to the conclusion on migration test, other parameters (saliva composition and level of agitation) could influence the test results.

From a practical point of view most stakeholders were satisfied with the method EN 12472 and thought that it could be applied to lead as well. The method is considered to be a practical solution for wear (and corrosion), the only critique that was brought forward was that the definition of the sample size has not been predefined. This could potentially lead to variations in test results. The aspect of trueness is less valid for this test as it is a practical test and the precision aspect is more relevant (no true level of wear and corrosion can be defined for the wide variety of articles that in practice will be tested).

All consulted experts considered the method to be reliable and suitable and no actions were identified in terms of improving the current test method EN 12472.

Derogations and alternatives

On the basis of its investigation, ECHA makes the following recommendations on each derogation in Table 1. However, ECHA considers the overall benefit from removing or amending the derogations is small and might not justify the resources needed to prepare an Annex XV dossier and for the opinion making in the Committees. This is a decision the Commission needs to make.

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Table 1. Overview of key findings and recommendations per derogation

<i>Derogations</i>		<i>Findings</i>	<i>Conclusion</i>
<i>Entry 63, para</i>	<i>Subject of the derogation</i>		
<i>8(e)</i>	<i>Keys and locks, including padlocks;</i>	<p><i>Testing with alternatives has led to products not meeting quality standards.</i></p> <p><i>The most advanced alternative, Si-based alloy, has decreased sliding behaviour and results in products with inferior surface quality.</i></p> <p><i>Currently there are no technically and economically feasible alternatives to lead in brasses and nickel silver in keys and locks, including padlocks.</i></p> <p><i>Industry testing not performed, due to derogation.</i></p>	<p><i>In the absence of information on migration from this article group, ECHA is not in a position to conclude on whether migration limits were fulfilled for these articles.</i></p> <p><i>Industry is advised to collect migration data in order to demonstrate compliance with the migration limits in entry 63 should the derogation be removed.</i></p>
<i>8(f)</i>	<i>Musical instruments;</i>	<p><i>Using Si and Bi lead-free alternatives for the bodies of brass instruments and bending parts result in reduced product quality and reduced recycling.</i></p> <p><i>The outer shape of the instruments and its parts as well as the bending parts are coated with silver, gold or varnish both for aesthetic reasons and for preventing lead migration.</i></p> <p><i>Few tests for lead migration conducted in accordance with EN 16711 indicate that both coated and uncoated brass mouthpieces containing approximately 3 % lead are compliant with the lead migration limit of 0.05 micrograms/cm²/hour.</i></p>	<p><i>Currently there are no suitable alternatives or definitive evidence supporting that the lead migration from the mouthpieces is within the limits.</i></p> <p><i>The derogation could be reconsidered for mouthpieces but only if, after further investigation, it is concluded that the migration limit can be met for both coated and uncoated brass and nickel-silver mouthpieces.</i></p>

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		<i>Lead content of solder is not accessible as solder is typically used inside the instrument. Lead-free solder is available on the EU market.</i>	
8(i)	<i>Religious articles;</i>	<i>No evidence was submitted that seems to indicate these articles containing lead are placed in the EU market.</i>	<i>In the absence of new information on possible alternative materials to lead in religious articles and on the impact of restricting lead in those articles, ECHA is not in a position to advise the Commission whether to continue exempting religious articles or not.</i>
8(j)	<i>Portable zinc-carbon batteries and button cell batteries;</i>	<p><i>Button cell batteries comply with limit of lead content of 0.05 % by weight of the article, while the limit is exceeded by the zinc-carbon batteries.</i></p> <p><i>A downward trend for the use of zinc-carbon batteries was identified, the market has shifted to a different battery systems, such as alkaline-manganese or nickel-metal hydride batteries, which are affordable and offer performance advantages. This trend is accelerated by old devices with low technical requirements being replaced by modern articles possibly reducing the need for lead based batteries.</i></p>	<p><i>There is currently no evidence that the derogation is still needed.</i></p> <p><i>Research from BAUA would suggest a negative trend in using these batteries and that more alternatives are available now. Examples of alternatives are:</i></p> <ul style="list-style-type: none"> <i>• Alkaline-manganese</i> <i>• Nickel-metal</i>

1. Problem identification

1.1. Introduction

Based on the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) on a restriction proposal made by Sweden, Commission Regulation (EU) No 628/2015 of 22 April 2015 was [adopted](#) amending restriction on lead and its compounds in entry 63 of Annex XVII of REACH.

Lead and lead compounds are present in consumer articles as intentionally added metallic lead, as an impurity or additive of metal alloys (particularly in brass), as pigments, and as stabilisers in polymers (particularly in PVC). Due to their mouthing behaviour, children, especially those under 3 years may be repeatedly exposed to lead or lead compounds released from consumer articles. Children are especially sensitive to lead exposure as their central nervous system is still developing, which can result in severe and irreversible neurobehavioral and neurodevelopmental effects.

Sweden proposed that placing on the market and use of lead and its compounds in articles supplied to the general public, and which can be placed in the mouth by children during normal or reasonably foreseeable conditions of use, should be prohibited if the concentration of lead (expressed as metal) is ≥ 0.05 % by weight of the product. Articles considered mouthable are smaller than 5 cm in one dimension or have a detachable or protruding part of that size. In line with the restriction of lead in consumer articles, a product with a lead content above 0.05 % w/w can be placed on the EU market only if it could be demonstrated that lead migration does not exceed the limit of 0.05 $\mu\text{g}/\text{cm}^2$ per hour. For coated articles, the lead content limit does not apply if the lead migration rate is within the limit value for at least two years of normal or reasonably foreseeable conditions of use of the article.³

Paragraph 9 of entry 63 of Annex XVII to REACH, requires the Commission to review the current restriction for lead in certain consumer articles by 1 July 2019.

The Commission has [requested](#) ECHA to prepare an evaluation report to enable the Commission to conduct the required review of entry 63 of Annex XVII to REACH.

Based on the findings of ECHA, the Commission will consider whether to request ECHA to prepare an Annex XV dossier in accordance with Article 69(1).

To assist the Commission to conduct the required review of the restriction, the Agency has investigated the:

- available analytical methodologies to determine migration of lead from the different materials,
- availability of alternatives for certain consumer articles, and
- suitability and availability of wear test methods.

ECHA has gathered information for its investigation through a call for evidence (CfE)⁴, a

³ https://echa.europa.eu/documents/10162/13563/lead_guideline_information_en.pdf

⁴ <https://echa.europa.eu/calls-for-comments-and-evidence/-/substance-rev/23601/term>

targeted literature review, and other sources⁵ to assess i) the availability of lead migration and wear test methods and their enforceability, and ii) whether there are suitable and available alternatives for the following four derogations made in the original restriction:

- keys and locks, including padlocks;
- musical instruments;
- religious articles;
- portable zinc-carbon batteries and button cell batteries.

1.2. Hazard, exposure/emissions, and risk

The Background Document to the opinions on the Annex XV dossier proposing a restriction on lead and its compounds in consumer articles⁶ outlines the severe and irreversible neurobehavioral and neurodevelopmental effects of chronic lead exposure to children. Blood samples of European children indicate blood lead levels (BLL) between 15 and 40 µg/L as a result of “background exposure” from food and non-food sources. Since there is no threshold for detrimental neurocognitive effects in children exposed to lead, any additional lead exposure should be avoided.

Articles containing lead are widely available for consumer use. These include clothes, accessories and shoes, furniture and interior decoration objects, keys and key rings, stationery, and others. In most cases, children’s exposure to lead and its compounds is unintentional and comes as the result of an oral contact such as chewing, sucking or swallowing articles or parts of articles containing lead. As outlined in the Background Document⁷, articles under the scope of the restriction account for 22 % of the mouthing activity of children. Ten percent of these articles are estimated to contain lead, with an average lead content of 1 %. Sweden, as a dossier submitter, determined that European children aged between 6 and 36 months would be the most affected, with between 5 % and 18 % of them being exposed to lead through unregulated articles.

Based on estimated mouthing time and lead migration, RAC estimated that the total quantity of lead mouthed by children at EU level per year is 367 g/year (if keys are excluded the total exposure is 251 g/year). RAC considers appropriate a lead threshold value of 0.05 % in consumer articles that can be mouthed by small children (under 36 months) and that lead exposure from mouthing consumer articles should not exceed 0.05 µg/kg bw per day. This exposure, also used for the restriction of lead in jewellery, is based on the assumption of one hour of mouthing per day and corresponds to a migration of 0.05 µg/cm²/h (0.05 µg/g/h), which potentially increases the blood lead level (BLL) by 1.2 µg/L, and has been found to result in an expected IQ reduction of 0.1 points). While some studies⁸ have shown that children (less than 36 months) spend 20 minutes a day sucking and chewing on objects other than food, toys and childcare articles, RAC and SEAC considered a more conservative

⁵ From a support contract with Eftec and with the help of the Forum (via a brief survey on lead migration test methods).

⁶ ECHA (2014)

⁷ <https://echa.europa.eu/documents/10162/04fed71b-ce93-b69b-8c7c-84d1c9437102>

⁸ Greene (2002) and Juberg et al., (2001)

mouthed duration of 1 hour a day, which may occur occasionally.

1.3. Justification for an EU wide restriction measure

The aim of the restriction is to minimise children's lead exposure from articles supplied to the general public and thus the possibility of adverse effects to their central nervous system. As no threshold has been found for the harmful effects of lead on the central nervous system⁹, and with a view to background exposure from diet and other environmental sources, any relevant lead exposure should be avoided as a matter of principle.

Since the risks related to lead in various articles for consumer use extend over all EU boundaries, a harmonised risk management measure within the EU is also appropriate in order to avoid trade distortions between and within actors of the supply chain that might inhibit the functioning of the EU internal market. The justifications provided in the Annex XV restriction report of Sweden and the opinions of RAC and SEAC are considered to be still appropriate.

1.4. Baseline

Not relevant for this report.

1.5. Context of this review - recap from the Background Document

Lead may be present in a variety of articles not only as part of the metal alloy, but also certain lead compounds may be used as pigments in coating of items. In most cases, lead has been identified as additive/impurity in metal alloys and pigments. Stabilisers were only identified as the probable source of lead in a minor share of articles for consumer use.

The product categories which may contain lead considered in the Background Document to the opinion on the Annex XV dossier on lead and its compounds in consumer articles¹⁰ are: clothes, accessories and shoes, furniture and interior decoration objects, articles for sports and leisure, keys and key rings, stationery, outdoor items and coated articles. In the Background Document it was reported that based on statistical data collected from the Prodcom database (2011), the EU production of these articles accounted for approximately 24 % of their total supply in the EU market, whereas import accounted for 76 %. As illustrated in Table 2, in 2011 a total of 8.05 Billion articles from the specified categories were produced in the EU, 15.37 Billion articles were imported, and 3.00 Billion articles were exported. As outlined in the Background Document, the market share of articles containing lead is estimated at 10 % with a lead content up to 4 %, and an average value above 1 %.

⁹ Reconfirmed in the lead in PVC restriction discussions (link to RAC opinion).

¹⁰ <https://echa.europa.eu/documents/10162/04fed71b-ce93-b69b-8c7c-84d1c9437102>

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Table 2. Compiled statistical data (2011) for each subcategory of articles in quantity (pieces)

	EU production	Export	Import	Net supply to EU market	EU Production, % of total supply	Import, % of total supply
Clothes	1205 M	674.3 M	9423.4 M	9953.7 M	5	95
Shoes	476.5 M	186 M	2509.8 M	2800.3 M	17	83
Accessories	273.5 M	213.8 M	1885.3 M	1945 M	4	96
Stationery	5751.3 M	25.9 M	4135.9 M	9861.4 M	47	53
Interior decorations	720.7 M	73.6 M	199.7 M	846.8 M	76	24
Sports and leisure	0.1 M	0.4 M	7.6 M	7.3 M	-5	105
Childcare articles *	4 M	2 M	8 M	10 M	21	79
Total	8045 M	3002 M	15 373 M	20 412 M	24%**	76%***

*) If not reported in any other subcategory, this category includes only baby carriages and parts of such

***) Example on the calculation of market shares. % EU production of total supply = (8

045 234 559 - 3 002 252 431) / 20 411 726 027 = 0.24 = 24 %

***) % Import of total supply = 15 373 116 562 / 20 411 726 027 = 0.75 = 75 %

The Background Document reports that the total number of enterprises in sectors that are (partly) involved in the manufacturing and sales of articles for consumer use in the EU in 2009 were close to 735 000, with small and medium sized enterprises accounting for more than 99 %. In the RAC and SEAC final opinion, it was highlighted that alternatives for the uses of lead under the scope of the restriction exist at comparable prices.

Because of their properties, lead and lead compounds are present in consumer articles as metallic lead, additive or impurity in metal alloys, pigments, and stabilisers in polymers.

Metallic lead is used for a small share of specific consumer articles, mainly as weights where the lead is used for its high-density property. Examples of articles which fall in the scope of the restriction are curtain weights (about 70 % lead content), while an example of derogated articles containing metallic lead are keys and locks.

Lead in metal alloys could be found in various articles in the clothes and accessories categories, for example as small metallic parts like buttons, buckles and zippers. Where aware producers and suppliers have substituted lead in such uses. However, before the restriction on lead and lead compounds in consumer articles entered into force, they were not always aware of the presence of lead in different metal parts of consumer articles. In most cases lead was not intentionally added (i.e. to achieve specific functions) in metal alloys but was present

as an impurity.¹¹ In certain cases, lead was added intentionally for its physical functions, such as acting as lubricant and hence providing mechanical workability or for achieving glossy surface effect.

Lead pigments could be found in a variety of accessories and clothing articles, including plastic prints on textiles and as surface paints in other group of articles. Lead was used for its property of increasing paint durability and corrosion resistance. Additionally, a 2012 report on the current and future status of the lead-based paints and pigments in Asia and the Pacific suggested that 75 % of these countries still use lead in products such as toys and consumer goods. Therefore, it was seen to be possible at the time that lead was present in articles imported in the EU (Murao and Ono 2012).

Lead-based stabilisers in PVC polymers could be used for textile prints, reflective bracelets, interior decoration and other firm articles. In plastic products, lead extends article's service life and fulfils requirements for heat endurance. Lead could also be found in consumer articles as a result of using recycled plastic.

As outlined in the Background Document¹², economically and technically feasible alternatives are available on the market for almost all uses of lead. For instance, concrete, tin, iron, zinc, copper, bismuth or silica are possible alternatives for lead in metallic materials or as an additive in brass alloys. Lead pigments may be substituted with various organic or inorganic colouring agents without the need of new equipment in most cases. The most common alternatives for lead in stabilisers in rigid PVC are calcium/zinc stabilising systems¹³.

2. Keys and locks, including padlocks

2.1. Rationale for the derogation

The following arguments for a derogation of keys and locks (incl. padlocks) were given in the Background Document to the opinions on the lead in consumer articles restriction proposal: *“RAC has indicated a potential risk from keys and padlocks, however SEAC has not been provided with sufficient information on the availability of alternatives and possible socioeconomic impacts to question the inclusion of the exemption. The public consultation on the SEAC draft opinion did not yield more specific socioeconomic information but did confirm an overall support of the responding parties to this derogation. The responses also highlighted that lead free keys – made from harder materials – deteriorate faster, and result in a shorter life time of the lock.”*

Further justifications are available in Appendix 15 of the Background Document, which provides a summary of the stakeholder consultation.

2.2. Information received on alternatives

For these items specifically, six stakeholders submitted their comments in the call for

¹¹ Yet small metal parts from clothes, shoes and other consumer articles have rarely been recycled and represented at the time of the restriction a marginal share of the total metal use in the EU. Provided the small quantities used, there is a wide range of available lead-free alternatives.

¹² ECHA (2014)

¹³ ECHA (2018b)

evidence, namely a joint submission by the European Copper Institute (ECI) and the Deutsches Kupfer Institute (DKI), the European Federation of associations of lock and builders hardware manufacturers (ARGE), the European Locksmith Federation (ELF), Wieland Werke AG and DIEHL Metall, Sundwiger Messingwerk GmbH & Co. KG. The submissions of DKI and ARGE represented the views of various stakeholders, for instance DKI approached major downstream users, whereas ARGE contacted suppliers of alloys and manufacturers of locks, keys and padlocks and provided an overview of their views.

The main **common arguments** in the call for evidence for a continuation of the derogation provided by the stakeholders representing the industry are the following.

- A number of alternatives for lead as alloying element in copper zinc alloys (brasses) have been developed, and out of them the technically most advance is lead-free silicon containing brass. While it has been successfully used in different applications, this alternative does not meet the specific technical criteria for manufacturing keys, locks and padlocks due to decreased sliding behaviour and inferior surface quality of the final parts.
- Lead-free alternatives are not recommended for the manufacturing of keys and locks, padlocks included, as they have decreased machinability and mechanical strength, which will require a complete reshaping of the manufacturing process to adapt the different materials in combination with high investments costs.
- There is no alternative for leaded nickel silver for the manufacturing of high-end key applications in the automotive industry and security industry. Tests with alternatives have led to inferior products that are more difficult to make, are less corrosion resistant (shorter service life of products) and are more prone to cracking of the alloy under temperature differences.
- Removing the derogation on keys, locks and padlocks would have implication on both manufacturers and users of these articles, such as an increase in material costs and a considerable negative impact on scrap recycling.

In conclusion, the commentators suggest that the exemption of keys, locks and padlocks, as identified by ECHA's Socio-economic Analysis Committee (SEAC) in the final opinion on an Annex XV dossier proposing restrictions on lead and its compounds in articles intended for consumer use, based on socioeconomic grounds, including the lack of suitable alternatives is still justified.

2.2.1. Quantity and technical functions of lead

In some alloys, lead is only present as an impurity, but in others it has a technical function. Where lead is regarded as an impurity, it can be removed without impacting the quality of the final product, although it is not always feasible to remove lead from an alloy. However, in alloys where lead has a technical function, any lead-free alternatives would need to compensate for / replace the properties provided by lead. If the lead-free alternative cannot replicate these properties, it may adversely affect the quality of the final product, and for keys and locks, the quality of the final product is imperative.

The European Federation of Associations of Locks and Builders Hardware Manufacturers (ARGE) is a European trade association and Wieland-Werke AG is a large German manufacturer of semi-finished products representing important stakeholders in the keys and lock industry. These stakeholders revealed that over the past couple of decades the key and

lock industry has aimed to lower the lead content as much as technically possible without compromising the quality of the articles produced. Research into lead-free alternative materials is continuously being carried out. The results of this research are discussed in Section 3.1.3. According to ECHA (2014), stakeholders have stated that using leaded-alloys to produce locks and keys extends the working-life of factory machinery, lowers the carbon dioxide emissions from the production process and it reduces the need for emulsifiers and oils.

In the manufacturing of keys, locks, including padlocks typically two lead-containing copper alloy families are used: lead-containing copper zinc alloys (brass) and lead-containing copper nickel zinc alloys (lead-containing nickel silver). The precise composition of these alloys follows international standards¹⁴ issued by the European Committee for Standardization (CEN) and the British Standards Institute (BSI).

Keys for automotive applications and high security cylinder locks are mainly manufactured using nickel silver alloys containing up to 1.5 % lead. On the other hand, low-end keys such as those often used for decorative purposes or furniture as well as the 'body' of the padlock are often manufactured from lead-containing brass. ARGE highlighted that the main components of almost all lock cylinders and many of the padlocks are made of brass with a lead content of 2.5 % - 3.5 %, (e.g. CuZn39Pb3 and CuZn40Pb2) and in many cases they are coated. Keys for lock cylinders and padlocks are predominantly made of either brass with a lead content of 2.5 % - 3.5 % or nickel silver with a lead content of 1 % used for high end keys (e.g. in CuNi13Zn24Pb1). Brass keys are sometimes nickel coated for marketing purposes as shiny look is thought to appeal to the customers. Stakeholders, such as ARGE and the European Copper Institute, revealed that lead is added in these concentrations (between 1.0 % - 3.5 %) as lead has a lower melting point than the other two primary constituents of brass: copper and zinc. Thus, the lead migrates towards the grain boundaries in the form of globules as the alloy starts to cool after casting. This has several beneficial effects on the alloy, improving the following properties: machinability, sliding/gliding, mechanical properties, tightness, reliability of contacting, and corrosion resistance.

For keys and locks (incl. padlocks), the main technical function of lead is to achieve good mechanical machinability. Lead improves the machinability, especially the milling and drilling operations, enabling the production of high-precision geometry articles, such as keys with specific features. As a chip-breaker, lead prevents the production of large chips during mechanical treatment and avoids damaging the product itself or the production tools, resulting in extended tool lifetime, higher productivity and less usage of resources together with a high quality surface of the machined material. On the contrary, brass with low (<0.01 %) lead content curls into 'tufts' and spirals when machined. With increasing lead content, the pieces of brass become smaller, and at a lead content of 3.0 % - 3.5 % they become 'chips'. This function of lead in brass is imperative to automated machining as large spirals of brass can easily damage the factory equipment. This disruption to production would be expensive to manufacturers who would need to either significantly reduce production and/or reduce the automation of their production process. Figure 1 illustrates the different chip sizes depending on the lead content.

¹⁴ <https://copperalliance.org.uk/knowledge-base/resource-library/coppers-copper-alloys-designations-standards/>

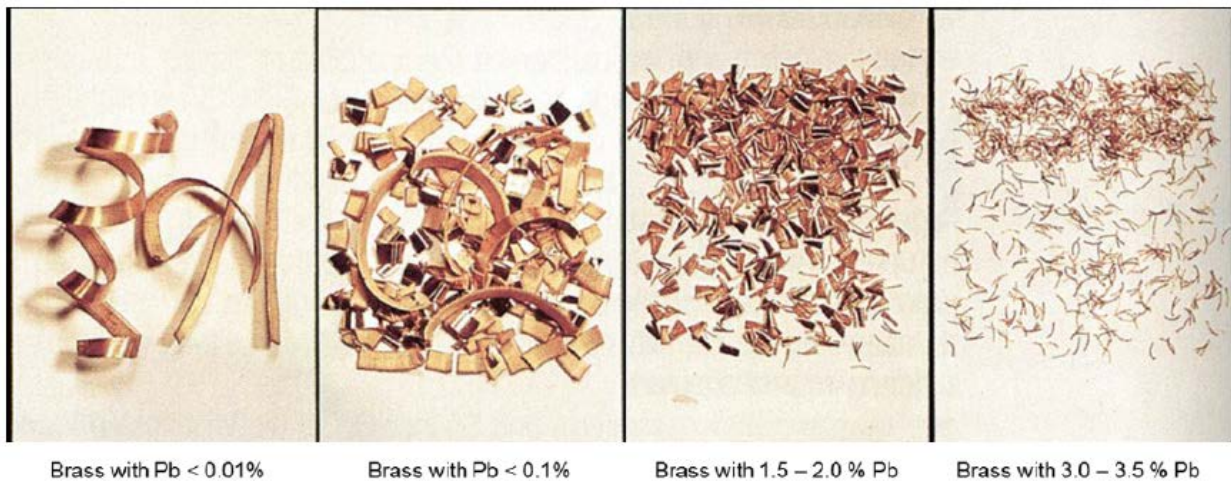


Figure 1. Chip sizes for brasses with different lead contents for identical processing parameters (Source: Wieland-Werke AG)

In addition to machinability, lead provides sliding/gliding properties to the material, preventing abrasion and other potential damage when inserting the key and operating the lock cylinder. This property prevents the blocking of a key in the lock. Furthermore, lead provides micro-lubrication during processing of the brass, which is sufficient to not require for applying additional oil or emulsions. The lubricating effect of lead also decreases the need for energy and resources.

Addition of lead in copper alloys is associated with mechanical properties such as ductility, hardness or breaking stress resistance. Lead containing alloys are less brittle, which makes keys stronger and less likely to break. On the other hand, keys made of lead-containing nickel silver with 1 % lead content are more brittle, which is a desired safety feature in automotive keys, where it is important that keys break upon impact (presumably for anti-theft reasons). Furthermore, using keys made of lead-containing nickel silver, which wears faster than the lock material minimizes the cost of maintaining lock-and-key systems since replacement of the key, is less costly than the replacement of the lock.

Lead increases the tightness in the alloy, which helps avoiding holes or material-distances when using copper alloys for casting final products. Furthermore, lead improves the reliability of contacting or the ability of the alloy to be used as contact-materials, e.g. electrical contacts and it is claimed to enhance corrosion resistance in copper alloys. As lead does not negatively interact with other alloying elements it is possible to add additional chemical elements to achieve better corrosion resistance. In the call for evidence, DIEHL Metall, Sundwiger Messingwerk GmbH & Co. KG notes that leaded nickel silver is a tarnish resistant material often used for safety keys (automotive and household). This is because it not only demonstrates excellent 'stampability' and machinability, but the corrosion resistance is so superior that no plating of the safety keys is necessary.

Figure 2 shows how the European Copper Institute quantifies the improvements lead brings to the properties of brass alloys. The index used ranges from 0 to 10, with 0 is the worst and 10 is the best compared to available brass alloys. The figure aims to demonstrate how adding lead to a (lead free) alloy improves some of its properties. The blue line in the figure then show to what extent these properties are improved.

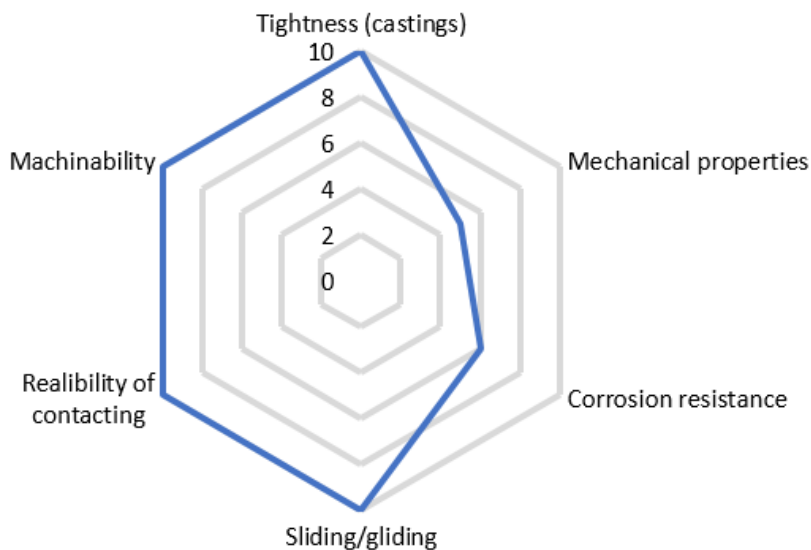


Figure 2. The six characteristics that lead improves in alloys and an index (0-10) to illustrate how effective the improvements are. The point of reference is the centre (0) which represents alloys without lead, the blue line shows the improvements made by adding lead. (Source: European Copper Institute, provided in response to informal stakeholder consultation)

2.2.2. Market for keys and locks

When the initial restriction proposal was assessed, there was no available information on the market shares of keys containing lead and lead-free keys. Sweden (2012) conducted tests on a range of consumer articles (see their Table 17 p. 50/224) including keys. Sweden assessed a total of 51 keys in Sweden and identified 34/51 (67 %) containing lead at an average concentration of 0.6 %. For their assessment of risk reduction capacity from the proposed restriction Sweden assumed 50 % of keys contained a lead content of 1 % as they noted that industry stakeholders indicated a higher average concentration of lead.

ECHA (2014) estimated that each year just over 2 billion articles assumed to contain lead are placed on the European market, which equates to approximately 83 000 tonnes of leaded copper alloys. 10 000 tonnes of the articles were said to fall within the scope of the restriction, with many of these being keys and locks. According to ECHA (2014), a multinational manufacturer of keys and locks, ASSA Abloy, reiterated that all keys and locks contain 'some lead', as brass encounters lead on production lines.

ECHA (2014) stated that the manufacturing of keys from semi-finished materials was mainly carried out by small and medium sized enterprises (SMEs) such as locksmiths and heel bars. Thousands of these businesses would be affected by a restriction on the use of lead, as lead-free alloys would require new machines to be properly processed. ARGE, who represents 95 % of the European market for locks and builders' hardware, agreed with this assessment and added that alongside the majority of family-owned SMEs, there were some suppliers with annual sales revenue in the range of €150 million – €2.5 billion and that there was one market leader who had annual sales of around €8 billion. The larger companies were stock-listed and often produced other articles as well as keys and locks.

Figure 3 illustrates the most common types of locks (surface mounted locks, padlocks, cylinder locks and mortice locks) on the European market.



Figure 3. Four common types of locks, a, b, c, and d refer to a surface mounted lock, a padlock, a cylinder lock and a mortice lock, respectively. (Source: ARGE)

Surface mounted locks (a) and mortice locks (d) are often used on doors and gates and are simple locks normally comprised of 3 parts: (i) an outer housing; (ii) a barrel (where the key is inserted); and (iii) a follower. As these three components are relatively easy to machine, they are made predominately from lead-free materials. At the time of the restriction entering into force, some surface mounted locks and mortice locks did contain lead. However, based on an interview with ARGE (October 2019), manufacturers have been successful in their research and development (R&D) and it is now possible to produce lead free surface mounted locks and mortice locks.

Padlocks (b) and cylinder locks (c) are often used for doors in buildings, gates and shutters and are more complicated locks comprising around 50 components of which almost all are made of lead-containing brass. ARGE estimates that 50 million locks enter the European market each year. Approximately 90 % of these are cylinder locks of which most contain lead. Of the cylinder locks that do not contain lead there are two groupings: (i) top-of-the-range cylinders purpose-built from stainless steel that are expensive and difficult to manufacture; and (ii) very cheap cylinders made of aluminium alloys, which are malleable and therefore easy to break. This is mirrored in the padlock market, which has both cheap, low-end aluminium alloy products and specialised high-end steel padlocks. However, most of the padlocks on the European market still contain lead.

ARGE estimates the annual quantity of keys placed on the European market to be approximately 200 million pieces. In addition, more than 8 million cars (2-3 keys & 3-5 locks each) are newly registered annually in Western Europe¹⁵ and 1 million motorbikes (2 keys & one lock each) are newly registered in the EU each year¹⁶. The European Copper Institute

¹⁵<https://de.statista.com/statistik/daten/studie/164769/umfrage/groesste-automaerkte-weltweit-nach-pkw-neuzulassungen/>

¹⁶ <https://www.acem.eu/>

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submitted evidence in the recent call for evidence that estimated that the average EU citizen carries 5-10 keys with them every day. This is supported by the fact that 200 million keys are placed on the European market each year, more than 90 % of which are made from leaded brass. Unlike with cylinder locks and padlocks, there is no lead-free upper-end product / material; just lower-end, lead-free cheap keys that are made from aluminium or steel alloys. Aluminium keys lose their shape after minimal use, whilst steel keys are brittle and often break themselves or the lock that they are paired with.

While most companies producing lock cylinders and padlocks also manufacture keys, some companies manufacture only keys and key blanks. Key blanks are semi-finished keys supplied to lock and key manufacturers as well as to locksmiths and key cutting services (for making duplicates of existing keys). According to information provided by ARGE, there are about 10 000 locksmiths and key cutting services established across Europe.

According to an estimation provided by the DKI/European Copper Institute, the total volume of brass and nickel silver used to produce keys, locks, padlocks and musical instruments is estimated to be 20 000 to 30 000 tonnes per year. It is difficult to provide a more precise estimate because these alloys are used for other applications as well and also the materials are often sourced via traders, and are therefore not reflected in the sales statics for keys, locks and padlocks. On the other hand, ARGE estimates that between 10 000 and 20 000 tonnes of copper alloy is used to make the 200 million keys and 50 million locks every year. A manufacturer of nickel silver (Wieland-Werke AG) indicated in the call for evidence that they supply many thousands of tonnes per year of lead-containing brass and lead-containing nickel silver directly to companies producing keys, locks, and padlocks, in addition to the volume of their material which smaller companies source through traders. The company estimates that hundreds of millions of keys are manufactured from their nickel silver material annually. One stakeholder provided information in the call for evidence indicating that the market for nickel silver key blanks is less than 2 000 tonnes / year.

PRODCOM is a database on Eurostat built on a survey for the collection and dissemination of statistics on the production of industrial (mainly manufactured) goods in the European Union, both in terms of value and quantity. The survey is based on a list of products which comprises of about 4 000 eight-digit codes related to industrial products and some industrial services.

The following PRODCOM code for keys was used to estimate the value of keys sold in the European Union:

- 25721350 – base metal keys presented separately (including roughly cast, forged or stamped blanks, skeleton keys)

As there are several PRODCOM codes that relate to locks in various environments, the codes were combined to make a total value for locks. The following codes were included:

- 25721130 – base metal padlocks
- 25721150 – base metal motor vehicle locks
- 25721170 – base metal furniture locks
- 25721230 – base metal cylinder locks used for doors of buildings
- 25721250 – base metal locks used for doors of buildings (excluding cylinder locks)
- 25721270 – base metal locks (excluding padlocks, motor vehicle locks, furniture locks, and locks used for doors of buildings)

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There were two other PRODCOM codes (listed below) containing locks, but they were not included as it would likely artificially inflate the estimated sales values:

- 25721330 – base metal clasps and frames with clasps, with locks (excluding fasteners and clasps for handbags, briefcases and executive-cases)
- 25721370 – base metal parts for padlocks, locks and for clasps and frames with locks

The PRODCOM data, presented in Table 3 below, indicates that the total EU-28 annual sales value of keys was around €225 million in 2018. Whilst the value of the market grew between 2014 to 2018, the tonnage data suggests that the market for keys has been declining over time, which may in part be due to the emergence and adoption of keyless technology. The market for locks continued to grow between 2014 and 2018, both in terms of volume and value, with a market value of €3.5 billion in 2018.

Table 3. PRODCOM data between 2014 and 2018 for values and sold tonnage of keys and locks

Year	Keys		Locks	
	Production value (€million)	Sold tonnage (expressed in kilotonnes)	Production value (€million)	Sold tonnage (expressed in millions of units sold)
2014	208	9	3 212	666
2015	203	8	3 290	703
2016	206	8	3 340	762
2017	229	7	3 495	793
2018	225	6 (estimated)	3 501	798

Table notes:

1. Source – PRODCOM based on 1 PRODCOM code for keys and 6 PRODCOM codes for locks
2. Values and volumes relate to EU-28 values as reported in PRODCOM
3. The values have been rounded to the nearest million to avoid the impression of false accuracy

Italy seems to have sold the most locks within the EU (24.5 % of the European value (€) of key production in 2018), followed by Germany (21.6 % of the European value (€) of lock production in 2018). Other countries with high sales levels of keys and locks include Spain, France, and the UK.

2.2.3. Assessment of alternatives

At the time of the initial restriction it was the view of the Dossier Submitter and agreed by SEAC that there were no suitable alternatives to lead-containing copper and brass for the manufacturing of keys and locks.

During the call for evidence, stakeholders noted that even today there is no lead-free alternative for lead-containing nickel silver with similar machinability and combination of other properties such as mechanical strength, colour, corrosion resistance and resistance to tarnishing, especially for high-end key applications in the automotive and security industry.

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Although there are lead-free alternatives developed for free cutting brass – silicon (Si) and bismuth (Bi), primarily used in drinking water applications, these are not suitable for leaded nickel silver. As DIEHL Metall, Sundwiger Messingwerk GmbH & Co. KG and the European Copper Institute indicated: i) Si produces unwanted nickel-Si which renders the alternative completely unfeasible, and ii) even small traces of Bi in copper alloys can cause cold and hot cracking which renders the alloy useless.

Although Si and Bi are to some extent feasible alternatives for free-cutting brass, these 'lead free' alternatives have several issues to be taken into account. One issue noted by stakeholders was that the "lead-free" alternatives of Si and Bi actually contained up to 0.1 % lead and 0.25 % lead, respectively. Therefore some "lead-free" alternatives may still contain small amounts of lead. However, based on the derogation set out in paragraph 8(g) these brass articles would not fall under the scope of the restriction, if the concentration of lead (expressed as metal) in the brass alloy does not exceed 0.5 % by weight.

The Danish EPA, commented in the six month public consultation on the restriction proposal that a range of lead-free articles are already available on the EU market. The European Writing Instruments Manufacturers Association provided evidence during the consultation on the SEAC's opinion, indicating that the 'latest knowledge' shows that lead-free brass had 50 % less machinability compared to lead-containing brass (of 3 %).

Since then, industry knowledge has improved on possible alternatives. A submission from The European Copper Institute in the call for evidence, revealed that there are currently three primary potential lead-free alternatives, each with their own advantages and disadvantages:

- Silicon (Si)
- Bismuth (Bi)
- Sulphur (S)

Si is widely regarded as the best of these three alternatives and has the largest market share of the lead-free alternative alloys. This is primarily due to its success in replacing lead in applications used by the water industry, where CUPHIN brass or Ecobrass has effectively replaced lead-containing brass. However, Si brasses have a distinct limit in sliding behaviour and inferior surface quality of the final parts which makes them less suitable to replace lead-containing brass in keys and locks. This argument is further supported by confidential tests submitted to ECHA by ARGE. Several members of industry, including the European Copper Institute and ARGE, noted that research on Si brass is still ongoing.

Firstly, tests conducted by IFT – Institute of Production Engineering and Photonic Technologies at TU Wien (Technical University of Vienna) on behalf a manufacturer of cylinder locks, padlocks, keys and other products demonstrated that lead-free brass (Ecobrass) has 80 % machinability in comparison to lead-containing brass (CuZn39Pb3). Additional properties include good cold formability, very good warm formability, good weldability and good polishability. Furthermore, the results indicated that a coated tool (name confidential) has enough workpiece quality and tool life for the machining process (drilling) of hard-to-cut material, such as Ecobrass. While the tool geometry can produce reaming quality in drilling, there is a potential to eliminate the reaming process, but also a need for optimisation of tool life. Secondly, a manufacturer of broaching tools, needed for manufacturing barrels (major component for lock cylinders and padlocks), has been conducting a test project with lead-free alloys, including Ecobrass at the Werkzeugmaschinenlabor of the RWTH Aachen (RWTH

Aachen is a Technical University). While Ecobrass seems to be the least compromising material, it was emphasized that all broaching tools used for broaching the profiles in the barrels have to be developed from scratch, including finding the most appropriate material for the tools.

According to the European Copper Institute, Bi brasses have chip breaking qualities, which is an important feature for the lock and key industry. However, Bi and its salts are toxic¹⁷. In addition, when Bi is combined with other alloying elements, highly efficient copper recycling loops are destroyed. The European Copper Institute estimated that, in 2010, these copper recycling loops provided the EU with 44 % of its annual copper supply. According to Wieland-Werke AG, copper scrap must be completely free of Bi if it is to be recycled; even if just 1 kg of Bi is in 4 000 kg of copper scrap, all of the scrap is deemed unusable. Wieland-Werke AG, notes that *"Bismuth-containing alloys are brittle, particularly at elevated temperatures. As a result, severe cracking has to be expected during hot working or use, even at very low contents of Bi (> 0.0005 %). For their original field of use (drinking water application) this is not problematic since no hot working operations are necessary during production. But for other applications which require hot working operations, already small amounts of Bi lead to such embrittlement of the copper alloys that further processing is impossible"*. Consequently, it would be imperative for copper scrap not to be mixed with Bi-alloys, which in practice is unlikely as Wieland-Werke AG, notes that *"experience shows that this is not possible in practice in particular if the materials are delivered into similar applications/markets. Scraps will always be mixed to some extent"*.

Sulphur brasses have also been successful in lead-free drinking water applications. ARGE commented that this is a relatively new alloy family, and as such, there is less information on sulphur-brasses compared with the other two alternatives (Si and Bi). Hence, ARGE argued that it was too early to determine whether sulphur brasses are viable alternatives to lead-containing alloys, as these brasses need further testing to determine whether they are feasible.

ARGE indicated that one typically sized company engaged a university to conduct research into lead-free alternatives in alloys for keys and locks. This research costed €130 000. Based on the number of R&D studies that ARGE are aware of, they estimate that somewhere between €1m-€10m has already been spent on trying to find a lead-free replacement for lead in keys and locks over the past couple of decades. Confidential data provided by ARGE to ECHA, shows that several companies have undertaken R&D themselves or funded university programmes researching possible alternatives. In addition to the two confidential reports mentioned above, where companies have tested manufacturing keys and locks with Si-based material ('Ecobrass'), three more confidential reports confirm that substituting lead with lead-free material in copper alloys is not feasible due to decreased machinability and mechanical

¹⁷ Bismuth has some toxicity but is commonly regarded as the least toxic of the heavy metals (i.e. less toxic than lead). Bismuth compounds are used as antiacids (e.g. PeptiBismol) see -

https://www.ema.europa.eu/en/documents/mrl-report/bismuth-subnitrate-bismuth-subcarbonate-bismuth-subgallate-bismuth-subsalicylate-summary-report-1_en.pdf. Bismuth metal and most of its compounds are not classified under REACH: <https://echa.europa.eu/substance-information/-/substanceinfo/100.028.343>, <https://echa.europa.eu/registration-dossier/-/registered-dossier/11383/2/1>, <https://echa.europa.eu/registration-dossier/-/registered-dossier/5663/2/1>

strength of the lead-free alternatives.

Firstly, a company tested the bending point (torque) of keys manufactured from lead-free material (Pb content below 0.01 %), and concluded that they have a lower bending point of approximately 9.35 % on average, thus resulting in a 10 % increase in key breakages. Secondly, another company tested the machinability of a lead-free material (name confidential), for manufacturing the main components of a lock cylinder, concluding that the lead-free alloy is not to be recommended mainly due to unsatisfactory machinability. Thirdly, a major producer of cylinders, keys and padlocks who has conducted a market research and an internal project to use lead-free brass reported that lead-free brass alloys do not assure the same level machinability. Thus, from a manufacturer point of view using lead-free alloys will require a complete reshaping of the manufacturing process to adapt the different materials in combination with high investments costs.

At this stage, there does not appear to be one alternative that can replace all the functions of lead in copper alloys. Thus, lead is likely to be replaced by a combination of different elements, as opposed to the like-for-like alternatives suggested so far. Moreover, different alternatives will likely be used for different applications, as alternatives suitable for the provision of drinking water will not necessarily work for keys and locks, and vice versa.

Whilst there does not seem to be a consensus on suitable alternative alloy(s) for keys, it is important to consider alternatives to keys and locks themselves – for example, keyless technology is becoming more common. Based on a variety of sources (NY Times, 2018; CNBC, 2014; Edmunds, 2018), it was estimated that in 2018 keyless cars accounted for 62 % of the new cars sold in the US and this number grows each year. The EU produced 16.5 million cars in 2018, and if only half of them are keyless, then 8.25 million cars entered the European market without the need for lead-containing keys (ACEA, 2019). This technology, pioneered in automotive vehicles, is spreading into other markets; large key and lock manufacturers such as Yale and ASSA Abloy now sell keyless locks to homes, called Smart Locks or Digital Door Locks, respectively (see Figure 4). Although digital keyless technology is still in its infancy, they may be viewed as technically and economically feasible alternatives to some users of lead-containing keys.



Figure 4. Yale's range of digital door locks: image (a) shows a keyless digital door lock and image (b) shows a smart door lock. Source: <https://www.yale.co.uk/en/yale/couk/smart-living/smart-locks>

2.2.4. Removing derogation scenario

Under this scenario, the existing derogation set out in paragraph 8(e) of the Annex XVII entry 63 would be removed after a transition period (yet to be defined). This would mean that after this transition period:

- Keys and locks (incl. padlocks) shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0.05 % by weight, and those articles or accessible parts thereof may, during normal to reasonably foreseeable conditions of use, be placed in the mouth by children.
- Keys and locks (incl. padlocks) may continue to be placed on the market or used in articles supplied to the general public where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0.05 µg/cm² per hour (equivalent to 0.05 µg/g/h). In addition, for coated articles, it should be demonstrated that the coating is sufficient to ensure the release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article.

It is not in the scope of this report to assess the health benefits of removing the restriction. Yet it is worth noting that keys and locks remain a major source of lead exposure to children. A National Authority in Austria commented in the 6-month consultation period on the proposed restrictions that based on work conducted by the MAK Commission of the Deutsche Forschungsgesellschaft that they had concerns that "*keys seem to be highly attractive to young children and very often misused as toys*". There is a strong consensus that keys are easily mouthable, and due to the abrasive nature of their use, often have protective coatings worn away. RAC estimated that the children at EU level are exposed to 116 g/year lead as a result of mouthing keys, while the total lead exposure (excluding keys) from mouthing consumer articles is 251 g/year.

2.2.4.1. Affected actors

Removing the existing derogation would impact the entire key and lock supply chain i.e. manufacturers, locksmiths and end-consumers who may need additional / replacement keys for existing locks.

The use of lead-containing copper alloys for keys, lock cylinders and padlocks has become a de facto world-wide industry standard and an industrial 'must-have', for instance European manufacturers export keys, lock cylinders and padlocks into markets outside the EU. Since there are no lead-free alternatives with similar properties for the manufacturing processes for keys, lock cylinders and padlocks, manufacturing would be less efficient and would have to be re-designed partially, requiring considerable investments. Furthermore, the complexity of the manufacturing process would result in increase of manufacturing costs, which in combination with the higher price of the alternative will result in an increase of product cost and consequently prices for keys, lock cylinders and padlocks. The higher costs will significantly hamper European manufacturers exporting their products outside EU, whose products would not be cost-competitive against non-European suppliers which still use lead-containing alloys. As a solution, the European suppliers would need to manufacture both lead-free products for the EU market and lead-containing products for exports into non-EU/EEA countries. On the other hand, European manufactures might also take advantage of the potential lifting of the derogation, as non-EU manufacturers would also need to import lead-free keys, locks and padlocks and they are likely to experience even higher cost increase than European manufacturers. However, it is assumed (based on discussion with key-stakeholders) that there are more exports of keys, lock cylinders and padlocks from EU/EEA countries to non-EU/EEA countries than imports, thus lifting the derogation will be disadvantageous to EU manufacturers.

In terms of the types and number of companies affected, based on data provided by ARGE, the EU market for the manufacture of locks and keys is predominately made up of SMEs and a few large companies. Locksmiths and key-cutters, typically small or even micro-businesses, would also be affected. Existing end-users with locks and keys that contain lead may be affected if it is not (technically) possible to get additional / replacement keys for existing locks, resulting in the need to prematurely replace the entire lock and key system. Consumers seeking new locks would only be affected if there is a price and quality difference between the lead-containing keys and locks and their lead-free alternatives.

That said, the removal of the restriction would mostly impact padlocks, cylinder locks, and keys as it seems to have been possible to substitute the use of lead in surface mounted locks and mortice locks. It is unknown how many companies in the surface mounted locks and mortice locks sector have successfully switched to lead-free alternatives, so there may be differential impacts between manufacturers and one may expect some current/future 'first mover advantages' to those EU companies that have successfully substituted away from lead, if the derogation no longer applied to surface mounted locks and mortice locks.

2.2.4.2. Most likely response to removing the derogation

Manufacturers

Manufacturers of padlocks, cylinder locks, and keys would have the following options:

- Switch to an alternative (lead-free) alloy, resulting into inferior products; Consumers would be affected by the higher price and lower quality of keys made with lead-free

alternatives.

- Switch to an alternative technology (e.g. keyless technology);
- Continue production for the non-EU market only;
- Cease production in the EU and relocate outside the EU to continue to supply the non-EU market; or
- Cease all production.

It is noted that for different products/markets different options may apply.

Some companies may, in the short-term, seek to switch to making keys and locks with lead-free materials such as Si-brass, but this would increase the costs of producing keys and locks and result in inferior articles produced. It is theoretically possible that over a longer period, suitable alternative alloys may be found, but there is no information indicating how long this process would take as no (known) R&D has been successful to date. However, ARGE estimate that SMEs would most likely cease production, as the costs required to purchase the alternative alloy(s) and replace contaminated / inadequate equipment would be too high.

Some alternatives do exist, so those that already manufacture keyless technology may see an increase in sales both in the short and long term. Based on limited market data, the number of keys that an average European would carry is expected to decrease over time as mobile phones and digital, smart locks and padlocks begin to take over the market as they are currently doing in the automotive industry.

Downstream users

Locksmiths and key-cutters would potentially be more affected than manufacturers, as the majority of these companies are small or even micro-businesses. They would no longer have access to 'blank keys' containing lead and it is highly uncertain if their existing equipment would be compatible with any lead-free alternatives. It is also unclear to what extent (if any) these locksmiths and key-cutters can switch to supplying and/or maintaining keyless technology. There was no information provided by stakeholders on how these downstream users may react, other than SMEs being unlikely to be able to afford to switch equipment until more suitable alternatives are identified and adopted.

Existing end-users of keys and locks that contain lead may be affected if it is not possible to get additional / replacement keys for existing locks, resulting in the need to prematurely replace the entire lock and key system earlier than required. Consumers buying new locks would only be affected if there is a price and quality difference compared to the lead-free alternatives. This could influence some end-users to purchase second-hand locks and keys, if lead-free alternatives result in less durable keys and locks.

Keys, locks and padlocks have an estimated lifetime of more than 20 years, hence even if all new products are manufactured with lead-free copper alloys, it will take decades until lead-containing articles will have disappeared from the market.

2.2.4.3. Costs of removing the derogation

To estimate the economic cost of removing the derogation for locks and keys, including padlocks, available information on the cost increase of switching to alternatives are used as a proxy, although none of the alternatives are deemed technically feasible. Several stakeholders noted the following types of costs associated with switching to alternatives:

Costs to manufacturers:

- One-off costs
 - R&D
 - Capital costs
- Recurring costs
 - Increased raw material costs
 - Increased processing costs
 - Reduced recycling, leading to increased energy and material consumption

In addition to the costs incurred by the manufacturers, there will be costs to the consumers due to inferior product quality.

One-off costs

R&D costs

As noted earlier, the industry is estimated to already have spent €1m-€10m on various R&D projects seeking to find suitable alternatives. Since there has not been a successful alternative identified for padlocks, cylinder locks, and keys, it is reasonable to assume that further R&D costs would be incurred to find both a short term option depending on the length of any transition period set and a long term solution. Since R&D to date is likely to have been based on a shortlisting of the most promising alternatives, it is possible that broadening the scope would result in higher costs, until the industry can build on the learning experiences from the existing R&D tests to mitigate some of these costs. However, as no information was provided by stakeholders, it is not possible to quantify future R&D costs.

Capital costs

If it was possible to find a suitable alternative, it may result in the need for all actors in the supply chain to update their equipment (tools and machinery) – both manufacturers of keys and locks as well as downstream users such as locksmiths. However, as no information was provided by stakeholders, it is not possible to quantify future capital costs.

Recurring costs

Cost of raw materials

An estimate of the costs of substituting lead-containing brass with Si-containing brass (CW724R) if the derogation was removed have been provided by Wieland-Werke AG. A Si-brass bar is €1 700 more expensive per tonne than its leaded-brass equivalent. This increase in cost primarily comes from the higher copper content of the Si-brass. Using the €1 700 unit cost, Wieland-Werke AG estimated the increased cost from raw materials to be around €51 million to €75 million/year based on the volumes of lead-containing brass and lead-containing nickel silver in keys, locks, including padlocks, and musical instruments of 20 000 to 30 000 tonnes/year.

The European Copper Institute estimated that if the derogation was removed for keys and locks, the industry would substitute the leaded brass with the best alternative, Si brass. Using a yearly figure of 49 000 tonnes of copper brass alloys containing >0.05 % lead, the stakeholder estimated the cost of replacement (of lead-containing copper) at approximately €119 million a year. However, the yearly tonnage of copper brass alloys used just for locks

and keys is lower than 49 000 tonnes, so the total costs would also be lower.

As noted in Section 2.2.2, ARGE approximate that between 10 000 and 20 000 tonnes of copper alloy is used to make the 200 million keys and 50 million locks per year and DIEHL Metall, Sundwiger Messingwerk GmbH & Co. KG provided information in the call for evidence indicating that the market for nickel silver key blanks is less than 2 000 tonnes per year. A mid-point on both estimates, gives a total weight of 16 000 tonnes per year. Using this tonnage estimate and the additional raw material cost (and processing cost) of €1 700/tonne, gives a total annual additional cost of around €27 million per year.

Processing costs

As discussed in 2.2.3, lead provides an array of technical functions in copper brass. One of the main benefits is the machinability of the alloy. This has enabled easy and fully automated processing, which currently cannot be achieved using alternative alloys. Therefore, one of the main factors for there being a higher cost of production will come from the need to replace existing automated programmes. ARGE explained during an interview; that in some cases, automated production will need to cease completely as some processes will need to be separated into individual processes. This will impact the speed of production, which would further make manufacturing more expensive. The €27 million per year estimate (above) is based on a unit cost of €1 700/tonne which is thought to include the additional processing costs.

Reduced recycling

As mentioned in Section 2.2.3, Si-brass increases the overall cost of keys and locks as due to its increased copper content and inability to be recycled. Due to the lack of lead, the end-of-life scrap can no longer be sold to a fabricator (fabrication involves the creation of a metal product from beginning to end) but has to be sold to a smelter. While the fabricator pays for the entire alloy (copper and zinc), a smelter only rewards the copper content of the scrap minus a “processing charge” (smelter costs) to recover copper from the alloy. Wieland-Werke AG submitted in the call for evidence that this results in the value of the Si-brass scrap being worth €816 a tonne less than its lead-containing equivalent. When this is applied to their estimate of the volume for keys and locks and musical instruments of approximately 30 000 tonnes a year, the total reduction of the scrap value would be around €24.5 million per year. Using the earlier estimated mid-point of 16 000 tonnes per year, this gives total reduction in scrap value of around €13 million / year.

European Copper Institute submitted evidence in the call for evidence revealing that current ‘lead free’ alloys can contain up to 1 % lead content. This was due to often using recycled metals from within the EU and/or manufacturing lead-free articles in the same factories that manufacture products with lead containing alloys. Therefore, to produce truly lead-free articles, one would need to remove recycled / recyclable lead-containing metal alloys from the EU to other third countries (which also has an environmental impact) and the additional cost of requiring virgin lead-free metals to be purchased.

Additionally, new factories and machinery would have to be installed in separate buildings, to avoid cross-contamination from lead-containing metals. This would dramatically increase the production costs as recycling only uses 20 % of the energy required compared to primary metal production. Moreover, the reduced energy efficiency will negatively impact the environment by increasing overall energy consumption. Therefore, with far lower rates of recycling and increased energy consumption, this would result in increases in both

environmental and economic costs from using lead-free alternatives. However, no monetary estimates were provided by stakeholder on these increased economic and environment costs.

Inferior product quality

FITCO S.A, a specialist copper alloy processing company, commented during the 60-day consultation on the SEAC opinion. They noted that the socio-economic effect of a concentration limit of 0.05 % lead in brass alloys would affect 11.3 % of all consumer articles on the European market. This will result in severe adverse impacts both for industry and society - especially in cases where the substitutes (Si and Bi) do not provide the required functionality. For example, inferior anti-corrosion properties will reduce the lifespan of keys and locks. For locks this will artificially push consumers to purchase more expensive, robust locks as cheaper alternatives would not provide the basic level of protection that the consumers have become accustomed to. For keys, there are no high-end, lead-free alternatives available, which means that they would need to be replaced more frequently. It has not been possible to derive the costs of premature replacement or transition to high-end products.

Price increase for consumers

If the cost increase for manufacturers is passed on to the consumer, the abovementioned costs would be reflected in increased product prices. Based on communications with ARGE on 1st October 2019, as a best-estimate they suggest the price of lower quality lead-containing products would increase by 15-25 %, but higher-end, more robust locks and keys could increase by as much as 100 %. It should be highlighted that consumer costs from increased prices of locks cannot be added to the cost to manufacturers, as this would lead to double counting. If the increased production costs are fully transferred to the prices, the costs to the manufacturers and the cost to consumers from increased prices of locks should be equivalent, meaning that either would accurately represent the one-off and recurring costs of manufacturing the products.

2.2.4.4. Total costs

The current information available does not allow us to estimate the total cost to the manufacturers and consumers. The estimates provided below must therefore be considered in terms of order of magnitude, rather than accurate cost estimates.

For the purpose of estimating total costs to society from removing the derogation for locks and keys, we are assuming all costs incurred by manufacturers will be passed on to the consumers through increased product prices. ARGE's estimated that 200 million new keys and 50 million new locks placed on the European market every year.

Extremely cheap and less resilient keys and locks (e.g. built-in suitcase locks) are made from aluminium alloy and would not be affected by a removal of the derogation. The highest quality and most expensive locks are made of stainless steel (assumed without lead-impurities), but these are difficult to manufacture and cost 10 times more than lead-containing locks. There are no equivalent 'very high-end' keys. However, these products only make up a small part of the market, and according to ARGE, more than 90 % of all locks and keys will fall under the scope of the restriction. This implies that annually at least 180 million keys and 45 million locks would be affected by a removal of the derogation.

Within the group of lead-containing keys and locks, there is also a variety of price-quality combinations. For simplicity, the products are divided into two groups: "high-end" and

“typical”. For the purpose of providing an order of magnitude estimate for the total costs of replacing lead in locks and keys, it is assumed that 90 % of the market falls under the category ‘typical’ products, whilst the remaining 10 % would be categorised as ‘high-end’ products.

On Master Locksmiths Association’s website (MLA 2019), the price of a standard door and window keys lie in the interval of €3 to €6. This would not include the cheaper keys, like padlocks keys, so the ‘typical’ key is expected to be cheaper than the lower end of this interval. The same webpage list prices for higher end security keys in the range €10 – €35. To ensure that cost estimates are not inflated, we will use a conservative price estimates of €2 per ‘typical’ key and €20 for ‘high-end’ keys.

Finding representative prices for locks are somewhat more difficult the range of prices is very broad and because one or more keys may be included in the price¹⁸ . Padlocks are generally less expensive than cylinder locks used for e.g. doors, often found in the range of €2 to €15 per lock, including key. Cylinder door locks would typically lie in the range of €6 to €100. Again, conservative price estimates are chosen, with a ‘typical’ price for locks and padlocks of €5 and a ‘high-end’ price of €50. Table 4 provides an overview of the assumed prices and the price increase estimates provided by ARGE.

Table 4. Prices and price increase for locks and keys in case of removal of derogations.

Product	‘Typical’ products		‘High-end’ products	
	<i>Price of lead-containing product</i>	<i>Price increase for lead-free product</i>	<i>Price of lead-containing product</i>	<i>Price increase for lead-free product</i>
Keys	€2	20%	€20	100%
Locks	€5	20%	€50	100%

Table note: The 20 % price increase for ‘typical’ products is derived by taking the average of the range of price increase (15-25 %) provided by ARGE.

Table 5 provides indicative estimates for the increased cost to society of removing the derogation for locks and keys, due to increased prices. It should be noted that the numbers do not reflect costs linked to inferior product quality and is thus likely underestimated compared to the actual costs. Based on the abovementioned assumptions and caveats, the total costs to society associated with removing the derogation is estimated to €690 million per year.

¹⁸<https://www.padlocks.co.uk/products/brass-padlocks> and <https://www.locksmiths.co.uk/faq/locksmith-prices/>

Table 5. Indicative increase in costs to consumers of switching to Si-brass, in €million.

No. of units	Typical' products			High-end' products			Increase in annual costs
	Share of affected products	Price increase	Total costs	Share of affected products	Price increase	Total costs	
180 million keys	90%	20%	65	10%	100%	360	425
45 million locks	90%	20%	41	10%	100%	225	266
Total costs for consumers	€690 - €745 million per year						

Table note: The 'typical' and 'high-end' prices of keys and locks were derived from desk-based internet searches to determine a reasonable range.

A simplified, alternative top down approach is to use the PRODCOM data, which shows that the market for keys was €225 million and locks €350 million in 2018, and assume that the 'average' price increase would be 20 % i.e. the 'typical' price increase shown in Table 4. This results in the added annual cost of using alternatives of around €745 million, which is in the same order of magnitude as was derived in Table 5.

To summarise, additional costs would be incurred for manufacturers of keys and locks due to higher raw material prices, changes to the production process and inferior machining properties of less suitable alternative materials. Assuming it is possible to pass on these costs fully to the consumers, this would result in higher purchase costs for consumers of keys and locks estimated using two simple methods in the region of €690 million to €745 million per year.

There will also be other non-monetised costs that are not captured by the increased prices of locks and keys. For example, if the alternative materials negatively impact the durability of keys and locks, this would lead to additional costs to consumers, as they will need to replace their locks and keys more frequently. Nor has it been possible to monetise the environmental costs from increased energy use caused by inferior machining properties of alternative materials. Furthermore, significantly reduced levels of recycling may not be fully reflected in the increased consumer costs of keys and locks, in which case the actual costs could be even higher.

2.3. Conclusions

At the time of the initial restriction it was deemed by the Dossier Submitter and SEAC that there were no feasible alternatives to lead-containing copper and brass for the manufacturing of keys and locks, including padlocks.

According to ARGE, companies have spent between €1 million - €10 million on R&D to find lead-free alternatives. However, no feasible lead-free alternative for lead-containing nickel silver with similar machinability and combination of other properties has been discovered. On the other hand, for brasses, the three most potential lead-free alternatives are silicon (Si),

bismuth (Bi), and sulphur (S). While these alternatives have been applied in other applications, they are not considered suitable for substituting lead in keys and locks, including padlocks for the following reasons:

- Si-brass, the most technically-advanced alternative, has been used in various applications, however, due to decreased sliding behaviour and inferior surface quality of the final parts, it does not meet the technical material requirement of keys, locks and padlocks. This argument is supported by a confidential test submitted to ECHA by ARGE, in which Si-brasses demonstrate 80 % machinability in comparison to lead-containing brass and in addition have severe implications on the material requirements for the broaching tools (all tools need to be developed from scratch).
- Bi brasses have very good chip breaking qualities, however the cracking of alloys containing Bi during hot use (even in very small concentrations) disrupts the highly efficient copper recycling loops. In addition, Bi and its salts are toxic. Hence, Bi is not considered a viable alternative by the industry.
- Another potential alternative for lead in brasses already applied in water drinking applications is sulphur. However, sulphur's potential for lead in brasses beyond water drinking applications has not been explored yet.

In case the derogation is removed, most likely the industry will switch to Si-brasses, which will result in a total cost increase for consumers of €690 million to €745 million per year as demonstrated in Table 5. The additional costs incurred by the manufacturers is a result of higher raw material prices, changes to the production process and inferior machining properties of less suitable alternative materials. In addition, other costs which have not been monetised and are not reflected in the calculations include less durability of keys and locks (due to brittleness) and the environmental costs from increased energy use due to inferior machining properties of alternative materials.

It should be also noted that the new trend for keyless solutions in the automotive sector is spreading into other markets, for instance large key and lock manufacturers such as Yale and ASSA Abloy now sell keyless locks to homes, called Smart Locks or Digital Door Locks (Figure 4). While still in its infancy, these keyless solutions may be viewed as technically and economically feasible alternatives to some users of lead-containing keys but not to all.

3. Musical instruments

3.1. Rationale for the derogation

The following arguments for a derogation of (parts of) musical instruments were given in the Background Document to the opinions on the lead in consumer articles restriction proposal: *“The Dossier Submitter had proposed that the derogation for musical instruments was no longer considered necessary as they are unlikely to be accessible to children and would thus not be regarded to fall within the scope of the proposed restriction. Comments in the public consultation questioned this within the context of the definition of accessibility. Although SEAC considered that there may indeed be grounds for agreeing with the public consultation comments, the Dossier Submitter chose to exempt musical instruments as a whole, in the original proposal, and in addition there was insufficient information on alternatives and possible socioeconomic impacts to include musical instruments within the scope of the restriction.”*

ECHA (2014) indicated the use of lead in wind instruments had not been verified through the

work carried out by the Dossier Submitter. Although parts of musical instruments did fall within the scope of the restriction, it was concluded that the solder used for brazing the brass instrument was primarily made from tin and mouthpieces (that are also manufactured from metal as well as rubber (ebonite) and wood materials), were exempt as the brass had a silver- or gold-plated finish. As SEAC considered that there was insufficient information on alternatives and potentially adverse socio-economic impacts of the restriction, it was suggested that a derogation would be put in place for the remaining instruments (ECHA, 2013). However, there was reason to believe that, through research, feasible alternatives to lead in musical instruments might become available in the future, which justified the review clause (after 5-years).

Further justifications are available in Appendix 15 of the Background Document¹⁹, which provides a summary of the stakeholder consultation to the draft SEAC opinion.

3.2. Information received

Many stakeholders provided information in the call for evidence. Comments received from stakeholders in Germany accounted for 18 out of 23 responses. In the call for evidence participated the European Copper Institute, Federal Association of German Musical Instrument Manufacturers e.V., IfM Institute for Musical Instrument Making e.V., and Chambre syndicale de la facture instrumentale. In addition, information was also provided by numerous companies and individuals producing and repairing musical instruments, including Benedikt Eppelsheim Wind Instruments, Wilhelm Heckel GmbH, Metallblasinstrumente Bernhard Willenberg, Buffet Crampon Germany GmbH, Master Music Srl, Petrof spol. sr.o. and several other companies which preferred their names to remain confidential.

The main **common arguments** provided by industry for a continuation of the derogation are:

- The reason for exemption of musical instruments, as identified by ECHA's Socio-economic Analysis Committee (SEAC) in the final opinion on an Annex XV dossier proposing restrictions on lead and its compounds in articles intended for consumer use, based on socioeconomic grounds, including the lack of suitable alternatives is still justified.
- In musical instruments lead is often an irreplaceable material for technical reasons, hence replacement with an alternative would mean research and years of testing before being able to offer new products on the musical market.
- Lead-free brass alloys have worse machinability and formability, decreased sliding and friction behaviour and decreased corrosion resistance and tightness in castings in comparison to lead-containing brass alloys. While machining of lead-free brass material is still possible, in some cases this would require a coating on the cutting tools, new tools and machines.
- A ban on the use of lead alloys in musical instrument would have serious economic and cultural implications for this small industry. Since musicians believe in the quality of the instrument made with specific materials, such as nickel silver, they will buy the instrument with the desired material specification globally. This would lead to moving

¹⁹ ECHA (2014)

the market of musical instruments to Asia.

- Silicon as substitute for lead in copper alloys does not improve the tightness, sliding properties and contactability of the alloy, which are essential parameters for the manufacturing and the quality of the brass instruments. For instance there is a strong impact on reliability and durability of the valves.

Lead-free solders are considerably more expensive and the durability and strength of solder joints is severely restricted. The higher melting temperature of the alternative material causes greater tension in the musical instrument and severely limits its acoustic quality.

3.2.1. Quantity and technical functions of lead

According to the call for evidence responses, for centuries musical instruments have been produced to have certain appearance, quality and acoustic properties. The look of the instrument can sometimes be viewed to be as important as the sound it produces, and the musical instruments are often crafted by specialist SMEs / family-run businesses. There are a wide range of musical instruments that contain lead, although not all fall within the scope of the restriction. Lead weights in piano keys, for example, are unable to be 'mouthed' as they are not detachable from the piano within the normal and/or foreseeable use of the instrument. Not all musical instruments, or parts of certain instruments, fall within the scope of the restriction. This makes it difficult to calculate the volume of lead contained in derogated (parts) of musical instrument placed on the European market. SEAC agreed with submissions received in the public consultation on the proposed restriction, which claimed that the derogation was needed as the scope's definition of 'accessible' would apply to certain parts of instruments (ECHA, 2014).

In the manufacturing of musical instruments lead-free brass and lead containing brass are complementary alloys used for different parts made with different techniques. Leaded copper alloys, with lead content between 0.5 % - 5 %, are used in brass and nickel silver parts for metal and woodwind instruments for its exceptionally good physical-technical properties, including machinability and formability, improved sliding and friction behaviour and increased corrosion resistance and tightness in castings. These properties allow for the shaping of the material in numerous production steps while eliminating the risk of breaking, tearing or ripping and also allowing for low wall thickness. Leaded copper alloys are used for specific mechanical parts of the instruments, such as mouth pieces, components for pipe connections, valves or drawing parts, precise key balancing of pianos and mechanical systems for the levers used for flaps and valves.

At the time of the restriction the European Copper Institute revealed that similarly to keys and locks, brass alloys used to create metal wind instruments, screws and bolts for wood wind instruments, solder for wind instruments and mouthpieces could contain up to 3.5 % lead. ECHA (2014) also reported that 'lead free' copper tin and copper zinc alloys used at that time contained up to 0.1 % lead, so would still be above the limit of the restriction's lead content. Thus, it was likely that most of the musical instruments that contained brass parts, solders or mouthpieces contained lead.

If the derogation would be removed the following parts/areas of woodwind and brass instruments would fall within the scope of the restriction due to use of lead:

- Bending parts / bodies of brass instruments
- Mouthpieces
- Solder

Use of brass instruments

The presence of lead serves different purposes in different parts of the instrument and is used in different forms and at different concentration levels. One stakeholder, specialised in manufacturing of wind instrument with over 190 years of experience, revealed that lead content in the solder used in wind instruments is typically 40 % whilst in the machined (brass) parts there is a maximum of 3 % lead. This was reiterated by two other stakeholders - a manufacturer of brass instruments and a musical instrument specialist, respectively, who then further broke down the content of lead in wind instruments as a whole:

- (i) The mean lead content of a metal wind instrument (without the mouthpiece) is 0.7-1.3 %.
- (ii) The share of the solder is about 0.2 % (as only small quantities are used within the instruments)
- (iii) Mouthpieces typically contain 3 % lead.
- (iv) Nickel silver contains 0.5-5.0 % lead. Lead is sometimes also used in brass instruments and woodwind instruments e.g. clarinets and oboes.

In brass wind instruments, there are turned / bending parts (e.g. supports, valves, lids and other smaller parts) which are made with an alloy that contains approximately 2 to 3 % lead. The function of lead in this application is similar to that in keys and locks, described in Section 2.2.1. As the alloy is softer when it contains lead, it stops twist tufts forming (where lead acts as a chip breaker) which dramatically improves the machining process. Due to the softer and more resilient alloy tubes/tunnels of instruments can be made with thinner walls which is integral to the instruments retaining its acoustic properties.

For cast components, the material needs to fulfil the requirement of the casting process, for instance, it is essential that the components have no defects, such as blowholes, which would impair the mechanical strength, acoustic quality and design. Smooth surfaces are needed not only for tonal, acoustic and/or optical reasons, but also for applying coatings. The outer shape of the instruments and its parts as well as the machined parts used within the instrument, such as stabilizers and valves are coated with silver, gold or varnish for aesthetic reasons but also to prevent leaching of lead.

Use in mouthpieces

Mouthpieces are considered independent, separate products which are not originally part of the instrument. They are, however, necessary for playing, and therefore included in this assessment of musical instrument lead content. In the call for evidence a specialist mouthpiece manufacturer (name confidential), noted that almost all mouthpieces are coated with gold or silver to ensure ease of handling, hygienic cleanliness, corrosion protection and to prevent lead contact with the musician. The function of lead in mouthpieces is the same as the function for the bodies of brass instruments: machinability and acoustic qualities. The brass used to produce the articles contains approximately 3 % lead.

During the call for evidence one company reported that the lead migration from mouthpieces they manufactured, both coated²⁰ and uncoated (containing 3 % lead) is within the limit of

²⁰ Coated items are first processed with the wear simulation test EN 12472 and then with EN 16711-3 to see how wear affects coatings and possibly migration of lead if the coating is compromised.

0.05 mg/cm²/hour (0.05 µg/g per hour). This information is based on tests for determination of lead release according to EN 16711-3 conducted by TÜV Rhineland on behalf of a mouthpiece manufacturer (name confidential). Silver plated brass mouthpieces (polished and degreased) and non-silver plated brass mouthpieces (polished and defatted) were tested and the results showed migration to be within the relevant limits. It is possible that other parts of musical instruments, containing similar lead content of around 3 %, such as the bending parts / bodies of brass instruments, might also be compliant with the limit of lead migration set in the restriction.

However, it needs to be considered if these migration testing results for mouthpieces represent an anomaly rather than something applicable to be generalised to all mouthpieces as the results stem from one source only. Furthermore, the test reports portray an unexpectedly low migration for brass item with lead content as high as 3 %²¹. Therefore, a careful consideration if EN 16711-3 as a testing method is possibly allowing false positives should be taken. This aspect will be discussed in Chapter 6.

Use in solder

Solders have a lead content of 40 %. They are used in brass or wind instruments and also for all the electric, electroacoustic or electronic instruments as solders enable to weld the electrical components that are necessary to make the instrument work. In brass and woodwind instruments at different stages of the manufacturing process are used different types of solders made from lead or silver. In solders, lead contributes for the optimization of resistance/stability of soldered joint, avoiding cold soldered joint and allowing for tension-free soldering due to low melting temperatures, which in turns ensure a long life quality product. 'Cold soldering' is when the solder and thereby the joint looks normal but they are weak and breaks under normal amounts of stress. One stakeholder noted that in solders, lead is used for achieving a uniform solder flow at the lowest possible temperatures (temperature difference of 22 % to lead-free solder) with maximum solder joint strength.

Furthermore, during the call for evidence one stakeholder emphasized that the lower melting point of lead-containing solder enables 'second soldering' to occur in certain instruments when the leaded solder is placed on top of unleaded solder, without the lead reducing the melting point of the second (leaded) solder. The lower melting point of leaded solders also means that separate joints that are close together can be soldered without damaging other joints. *Chambre syndicale de la facture instrumentale*, an international association, noted that lead-free solders are available, however, they are more complicated to make and require a welding station with a faster recovery time as using a regular station used for lead solders will damage the components. The same stakeholder also added that double soldering is integral to the fabrication process. There is a low risk of mouthing of solders, as they are either on parts which cannot be decoupled from the instrument or they are inside the instrument.

EEB and ClientEarth highlighted in the 6-month public consultation on the proposed restriction that some larger musical instrument manufacturers such as Yamaha had phased out the use of leaded solder already in 2004. EEB and ClientEarth pointed out that if one manufacturer could

²¹ RAC recommended a derogation for brass alloys in articles up to 0.5 % of content due to the results reported by the European Copper Institute indicating that the lead migration rate in saliva might exceed 0,05 µg Pb/cm²/h when the content of lead in the alloy is above 0.5 %. With lead contents of 3 % approximate migration can reach 0.2 µg (ECHA 2014, Urrestarazu et al. 2014)

successfully make the switch, then other manufacturers could as well. However, it was not specified whether Yamaha had stopped manufacturing instruments with leaded-brass, if or how they had to change their manufacturing process, as a result of the different physical properties of lead-free solders (explained further in Section 3.2.3).

3.2.2. Market for musical instruments

As previously mentioned in Section 3.2.1 the majority of manufacturers are SMEs and / or family-run businesses. Everything produced in a given year is not necessarily sold in that same year, meaning that some companies may hold large amounts of stock. For example, a manufacturer of mouthpieces for instruments, can at any given time have up to 20 000 mouthpieces in storage, lasting up to 3 years.

According to data provided by the Bundesverband der Deutschen Musikinstrumentehersteller, the annual tonnage used to manufacture musical instruments in Europe is in the range of 5 000 to 10 000 tonnes of copper alloy per year.

PRODCOM is a Eurostat database built on a survey for the collection and dissemination of statistics on the production of industrial (mainly manufactured) goods in the European Union, both in terms of value and quantity. The survey is based on a list of products which comprises of about 4 000 eight-digit codes related to industrial products and some industrial services²².

The following code was used for musical instruments (that would be within the scope of the restriction) sold in the European Union:

- 32201370 – other wind instruments

The following relevant PRODCOM codes (and their descriptions) were judged to include lead, but were not included in the group for musical instruments, as it was judged to artificially inflate the market value:

- 32201110 – acoustic new upright pianos (including automatic pianos)
- 32201130 – acoustic grand pianos (including automatic pianos)
- 32201150 – keyboard stringed instruments (including harpsichords, spinets and clavichords)
- 32201310 – keyboard pipe organs, harmoniums and similar keyboard instruments with free metal reeds
- 32201340 – accordions and similar instruments; mouth organs
- 32201510 – percussion musical instruments
- 32201600 – metronomes, tuning forks and pitch pipes; mechanisms for musical boxes; musical instrument strings
- 32202000 – parts and accessories of musical instruments

Table 6 below indicates the total EU-28 value for wind instruments was around €146 million in 2018 with sales of around 970 000 items. The market value and volume has been broadly stable over the last 5 years. It is recognised that only covering wind instrument means this is an underestimate of the total value of the market affected due to limitations with what PRODCOM covers in terms of musical instruments.

²² For more details see:

<https://ec.europa.eu/eurostat/statisticsexplained/index.php/Glossary:PRODCOM>

Table 6. PRODCOM data between 2014 and 2018 for values and sold tonnage of (wind) musical instruments.

(Wind) Musical Instruments		
Year	Production value (€ million)	Sold tonnage (no. of items – expressed in millions)
2014	142	0.99
2015	120 (estimated by PRODCOM)	1.2
2016	143	0.99
2017	140	0.97
2018	146	0.97

Table notes:

1. Source – PRODCOM based on 1 PRODCOM code for ‘other wind instruments’
2. Values and volumes relate to EU-28 values as reported in PRODCOM
3. The values have been rounded to the nearest million to avoid the impression of false accuracy

According to the PRODCOM data, the production of wind instruments is predominantly made in France (54 % of the European value (€) of wind instrument production in 2018) and Germany (37 % of the European value (€) of wind instrument production in 2018).

3.2.3. Assessment of alternatives

Musical instruments are required to have certain physical properties and acoustic qualities, whereby the technical functions of lead in musical instruments are discussed in Section 3.2.1. Both the Dossier Submitter and SEAC concluded that there were no feasible alternatives to lead containing copper and brass for the manufacturing of musical instruments (See Section 3.1 for further details). In the recent call for evidence, stakeholders presented similar issues, as they have either researched (unsuccessfully) to find a suitable alternative or are still currently unaware of one.

The three alternatives for lead in copper alloys, namely bismuth, silicon and sulphur and the respective considerations regarding their suitability, outlined in Section 2.2.3., are also valid for substituting lead in musical instruments.

Use in bending parts / bodies of brass instruments

For brass used in wind instruments the alternatives that have been assessed are the same as noted in Section 2.2.3.; Si, Bi and sulphur. As with keys and locks, these alternative materials encounter the same issues with tightness, machinability, reliability of contacting, sliding / gliding, mechanical properties and corrosion resistance. The quality of the instrument is integral to its function, so the alternative materials must be able to replicate the same properties as leaded brass. As with other articles that fall within the scope of the restriction, there are alternative materials that can be used, but they are widely regarded as inferior. The German Copper Institute noted that using Si and Bi lead-free alternatives resulted in reduced product quality and reduced recycling. Si alloys do not improve the tightness (of casting), sliding properties and ‘contactability’ (electroplating) of the product, which would have a strong (negative) impact on the reliability and durability of the valves on instruments.

Use in mouthpieces

In relation to mouthpieces, although there are lead-free alternatives developed for free cutting brass, there are no alternatives for leaded nickel silver, which is commonly used for mouthpieces. The two main lead-free alternatives for free cutting brass (developed for drinking water applications) are silicon (Si) and bismuth (Bi). However, DIEHL Metall, Sundwiger Messingwerk GmbH & Co. KG and the European Copper Institute have both indicated that the use of Si produces unwanted nickel-Si which renders the alternative completely unsuitable. Concerning Bi, as previously explained in Section 3.1.3 even small traces of Bi in copper alloys can cause cold and hot cracking which renders the alloy useless.

Musical instruments are required to have certain physical properties and acoustic qualities which cannot be fulfilled using these two possible alternatives. The technical functions of lead in musical instruments are discussed in Section 1.1.1. Several stakeholders have tried to find (unsuccessfully) a suitable alternative or are still currently unaware of one.

A manufacturer of mouthpieces, chimes, bells and accessories (name confidential) reported that the time and costs involved with trying to discover a suitable alternative to lead containing brass (and solder) are “very-time and cost-intensive”²³. In order to complete a full comparison of the materials, the company would need to buy different materials in small quantities (which would be expensive). This would also require production halts, as the equipment would need to be tested with the new materials. Again, this process would be very time consuming as the machines need to be thoroughly cleaned before and after every test as the shavings of different materials cannot be mixed. New machines would also have to be tested as the current infrastructure is likely not capable of processing the necessary range of different materials and their respective properties.

The same stakeholder also added that when testing new machinery, over 4000 new Computer Numerical Control (CNC) programmes would need to be re-written, as each of the large number of different mouthpieces the company manufactures requires a unique set of CNC programmes for the manufacturing process. The use of lead-free alloys would result in lower quality machining outputs, as the raw materials are harder. Tools would also wear out more quickly slowing down production and increasing the cost of processing. The surface texture would most likely deteriorate too, thus increasing the polishing requirements which is an associated danger for production accuracy. To compensate for this, an adjustment of the CNC programmes would be required, which again, due to the large number of programmes (4 000) would be extremely time-consuming.

There are other materials currently used to manufacture mouthpieces, including stainless steel²⁴, titanium and plastic²⁵. However, these seem to be niche markets, with stainless steel mouthpieces being expensive high-end products, whilst the plastic mouthpieces are affordable but presumably inferior to the brass mouthpieces. It is highly uncertain whether such alternative materials could replace lead-containing mouthpieces in all applications.

Use in solder

EEB and ClientEarth highlighted in the 6-month public consultation on the proposed restriction

²³ No monetary or quantitative estimate was provided.

²⁴ <https://www.gwmouthpieces.com/>

²⁵ <https://www.dawkes.co.uk/faxx-clear-plastic-trumpet-mouthpiece/010962>

that Yamaha had phased out lead in solder already in 2004. This was said to have paved the way for other companies to also phase out lead in solder. One stakeholder noted that there is a silver-based soldering paste available, however, it has a negative impact on the double-soldering process which involves leaded solder being placed on top of unleaded solder. This process works due to lead's lower melting point, which allows the leaded solder to be placed over unleaded solder without compromising the joint. Lead-free solders are commonly found on the European market, and some companies, such as Yamaha, have removed lead-solder from their production process altogether. This notwithstanding, and similarly to mouthpieces, the lead content is typically not accessible, as the solder is typically used inside the instrument and cannot be mouthed during normal or foreseeable use.

3.2.4. Removing derogation scenario

Under this scenario, the existing derogation set out in paragraph 8(f) of the Annex XVII entry 63 would be removed after a transition period (yet to be defined). This would mean that after this transition period:

- Musical instruments shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0.05 % by weight, and those articles or accessible parts thereof may, during normal to reasonably foreseeable conditions of use, be placed in the mouth by children.
- Musical instruments may continue to be placed on the market or used in articles supplied to the general public where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0.05 µg/cm² per hour (equivalent to 0.05 µg/g/h). In addition, for coated articles, it should be demonstrated that the coating is sufficient to ensure the release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article.

3.2.4.1. Affected actors

Removing the existing derogation would impact the entire musical instruments supply chain (i.e. manufacturers, suppliers, repairers, and end users of affected instruments). The musical instrument industry includes some big companies as well as a large number of small and micro-sized enterprises. The responses provided in the different stakeholder consultations indicated that no known alternatives would have the technical and economic advantages as lead-containing materials. It is expected that a transition to alternatives may require large up-front costs, due to requirements for new machinery and testing of materials, which would be particularly problematic for the smaller companies.

This issue was highlighted by one stakeholder (name confidential) which explained that it would be extremely challenging for them - as a small craft business, with a limited number of employees - to make the required changes in parallel with normal production without experiencing delays in the delivery of their products. Many of their customers value them for their short delivery times. It is unclear whether they would be able to bear the high

procurement costs for new tools, such as reamers²⁶, which are custom-made for them.

There will also be affected actors further down in the supply chain. Companies in the business of repairing instruments will likely have to invest in new instruments/machinery if the instruments are produced using lead-free materials, due to the different properties, e.g. machinability described in Section 3.2.3. The end-users may also be negatively impacted due to increased prices, if the manufacturers transfer the costs to the prices and through reduced quality of the products.

It is worth reiterating however, that many musical instruments, or parts thereof, containing lead is not expected to be included within the scope of the restriction. For example, lead used in piano keys or solders used inside an instrument will not be accessible to children and thus not affected by a removal of the derogation. Similarly, coated parts e.g. mouthpieces, will not be affected, as long as they fulfil the requirements of maximum migration rate of 0.05 µg/g/h for at least two years. Actors manufacturing, supplying, repairing or using such instruments, would therefore not be affected by a removal of the restriction

3.2.4.2. Most likely response to removing the derogation

Manufacturers of musical instruments and leaded solder would have the following options:

- Switch to alternative (lead-free) alloys and solders resulting into inferior products; Consumers would be affected by the higher price and lower quality of tones made with lead-free alternatives;
- Use coatings or lacquers to cover the accessible lead-containing parts of the instruments to ensure those articles fulfil the restriction limit of 0,05 % w/w or have a migration limit below 0.05 micrograms/cm² per hour;
- Continue production for the non-EU market only;
- Cease all production.

Some alternatives do exist, so for those companies that already manufacture lead-free instruments (or solder) it is likely that their sales will increase both in the short and long term. However, a large number of small and micro-enterprises who specialise in the manufacturing of certain musical instruments will likely cease production as the costs required to purchase the alternative alloy(s)²⁷ and replace contaminated / inadequate equipment would be too high. Whilst the additional costs are likely to be passed onto the customer in terms of higher prices for musical instruments, these smaller companies will be more affected than the larger companies who will have the financial capabilities to adapt their manufacturing processes from lead-containing to lead-free materials.

Consumers seeking new musical instruments would only be affected if there is a price and quality difference with any lead-free alternative products. One stakeholder (the UK Music Industries Association) communicated that some companies have concerns that removal of

²⁶ Illustrations of reamers specific for musical instruments can be found here:

<https://www.dictum.com/en/herdim-reamers-jbg>

²⁷ One stakeholder (Wieland-Werke AG) indicated that “the additional costs of Si-brass compared with Pb-brass is ca. 1.700 EUR/to. This difference results from the higher copper content of the Si-brass and from higher processing costs for the production of semi-finished products from Si-brass”.

the derogation would just increase the number of second-hand sales of instruments that contained lead, as these instruments would be judged to be 'better' compared to new lead-free instruments based on their visual and acoustic properties. This will necessarily only be a short-term solution, as the old instruments will be gradually phased out with increasing age.

3.2.4.3. Costs of removing the derogation

Estimating costs to society from removing the derogation for musical instruments is challenging, as there is a lack of information on the number and type of articles, or parts thereof that falls within the scope of the restriction. Additionally, it is expected that different applications of lead in instruments will be associated with different types of costs, so extrapolating using cost estimates from few stakeholders to the entire market would not yield meaningful results.

Several stakeholders provided cost information, but it has not been possible to verify whether the reported cost estimates would actually materialise, as it is unclear whether the parts of the instruments containing lead (and associated costs of using lead-free alternatives) would fall under the scope of the restriction. For example, some of the stakeholders that provided monetised cost estimates will most likely not be affected at all, as the lead-containing parts of their products would not be accessible to children. Table 7 provides a summary of the cost information provided by stakeholder in the musical instrument industry.

Table 7. Summary of cost information provided in call for evidence

Company description	Costs	Scope relevance
Manufacturer of mouthpieces	R&D to date – €20k - €25k per year, for four years	Not very relevant, as almost all mouthpieces are coated
Manufacturer of pianos	Added cost per instrument of €20, and reduced sound quality	Not in scope, as the lead is inside the piano keys
Metal wind instrument manufacturer	Relocation of EU manufacturing of 'elite' trumpets. SMEs at risk for full closure.	Some parts of product portfolio likely in scope
Importer of brass instruments	Stop import of brass instruments. €9.1 million of lost revenue per year	Some parts of product portfolio likely in scope
Manufacture of musical accessories, metronomes, tuning forks etc.	Processing cost increase by 250%	Some parts of product portfolio likely in scope
Industry association for manufacturers and importers of musical instruments	Impact on 1 500 to 2 000 people and revenue loss of €250 million per year.	Some parts of product portfolio likely in scope
Manufacturer of mouthpieces	Replacement costs of (old) reamers (drill bits) of €360 each, totalling around €90k.	Not very relevant, as almost all mouthpieces are coated

Table note: Mouthpieces not being in scope is contingent on sufficient coating ensuring maximum migration rate of 0.05 µg/g/h for at least two years.

Chambre syndicale de la facture instrumentale (CSFI), highlighted that using lead-free brass alloy for brass instruments, in particular the machined parts, would result in more labour and energy-intensive manufacturing process, multiplying by four the machinability time of the instrument's pieces, thus affecting the quantity of instruments produced. In order to overcome these challenges, companies need to invest in new machines requiring training of employees, new tools and new quality control process. However, these major changes could undermine musical instrument makers, having significant impact especially on small companies and craftsmen. In addition to increase, in material costs lifting the derogation would also have a considerable negative impact on scrap recycling. CSFI estimates that a new regulation on lead would impact between 1500 to 2000 staff and sales revenue of €250 million. While lead-free solders are available on the market they have different temperature recovery time, which would require manufacturers to change machines as well.

According to a manufacturer of musical accessories exporting to over 72 countries worldwide (name confidential), without adding lead, in certain cases, the processing costs could increase by more than 250 %, as the cutting speeds are lower and the service life of the processing tools shorter. Furthermore, the material costs are higher, while the surface quality, sliding and friction behaviour decreases. On the other hand, a manufacturer of mouthpieces raised concerns regarding potential trials with alternative materials, which would require significant amount of time and money. For the trials with different materials, the company would produce and compare blanks in small numbers with high prices. The inability to mass produce the test mouthpieces due to the need to clean the machines before and after every new material is tested is expected to lead to production failures. Furthermore, the company highlights that not only different production methods would likely be tested, but also the deteriorated surface texture will require more polishing, which would require the adjustment of over 4000 CNC programmes (discussed in Section 3.2.3). The company would also incur high procurement costs for purchasing 250 new custom-made reamers (€360 per reamer).

As explained in Section 3.2.3, lead-free alternatives are currently not able to reproduce the same properties as lead, leading to lower quality instruments. This will result in a consumer surplus loss for both the user of the musical instruments and the society at large by lessening the musical experience linked to high quality instruments.

Distributional impacts

For manufacturers already using lead-free materials, the removal of the derogation will have a positive impact on sales, as they will have a competitive advantage as first movers. However, if the acoustic quality of the instrument is impaired or the customer insist on specific material characteristics, they might self-import from outside EU, where manufacturers of musical instruments do not have to comply with the lead limits. On the other hand, a removal of the derogation may also reduce the competitiveness of the European market, as some of the largest manufacturer of musical instruments are located in Asia, including Yamaha which has already phased out lead in all their solders. It is uncertain whether increased market shares for companies like Yamaha would be a cost or (partly) distributional, as it might be the case that they have manufacturing sites in the EU supplying the European market.

Extrapolating from the responses to the stakeholder consultation, one can infer that lead-based materials are still in widespread use in Europe. The competitive disadvantage for these companies would be a loss of market shares in the EU to companies that have already phased out lead. Again, these impacts would be more severe for smaller companies, as they do not

have the advantage of economies of scale to begin with, and (temporary) loss in market share might not be bearable. Whether the competitive disadvantage will be a cost or benefit will depend on their ability to capture the lead-free share of the market.

3.3. Conclusions

Lead is used in woodwind and brass instruments in *the bending parts which are on the bodies of brass instruments, in mouthpieces and solders*.

For *bending parts / bodies of brass instruments* the alternatives that have been assessed are the same as for keys and locks, including padlocks, noted in Section 2.2.3.; Si, Bi and sulphur. As with keys and locks, these alternative materials encounter the same issues with tightness, machinability, reliability of contacting, sliding / gliding, mechanical properties and corrosion resistance. For instance, as highlighted by the German Copper Institute, using Si alloys would have a negative impact on the reliability and durability of the valves on instruments. While the bending parts (supports, valves, lids and other smaller parts) require approximately 3 % lead, as previously discussed in Section 3.2.1., the outer shape of the instruments and its parts as well as the bending parts are coated with silver, gold or varnish both for aesthetic reasons and for preventing lead migration.

In *mouthpieces*, Si and Bi are the two main alternatives for lead in free cutting brass. However, Si produces unwanted nickel-Si which renders the alternative completely unsuitable, while Bi and its salts are toxic. In addition, the same considerations of Bi outlined in Section 2.3 regarding the disruption of the highly efficient copper recycling loops due to cracking of alloys during hot use are valid here as well. The use of lead-free alloys would result in lower quality machining outputs, as the raw materials are harder. Tools would also wear out quicker slowing down production and increasing the cost of processing. On the other hand, there are no alternatives to replace lead in nickel silver, which is commonly used for mouthpieces.

There are lead-free alternatives to lead in *solders* available on the European market, and some companies have already switched to these alternatives. However, using lead-free solder has a negative impact on the double-soldering process and on the optimization of resistance/stability of soldered joint. Lead alloys on the other hand, allow for tension-free soldering due to low melting temperatures, which in turns ensure a long life quality product. It should be noted that the lead content is typically not accessible, as the solder is used inside the instrument.

4. Religious articles

4.1. Rationale for the derogation

There was no derogation proposed for religious articles in the initial restriction proposal by Sweden (2012), nor in ECHA's (2014) final Background Document and in the opinion adopted by RAC. A minority-vote on SEAC opinion raised the issue of the insufficient assessment of cultural, traditional and/or religious handcrafted figurines and similar articles and the potential adverse impacts for small and micro-enterprises manufacturing such articles. The European Commission took this into account in their decision, concluding that the impact of the restriction on lead in religious articles was not fully assessed and it was therefore appropriate to exempt those articles from the scope until a detailed assessment of the impacts can be carried out.

4.2. Information received

4.2.1. Quantity and technical function of lead

During the restriction process for lead and its compounds in jewellery articles, the technical function of lead in crystal glass, enamels and precious and semi-precious stones was discussed. Lead was said to be used in these products in order to obtain certain properties such as colour, brightness and stability. Since glass, enamels and precious stones may also be used in religious articles, this rationale also applies to religious articles.

4.2.2. Market for religious articles

Due to the lack of responses from relevant stakeholders, not much is known about the market for religious articles. However, ECHA's guideline on the scope of the restriction²⁸ includes a description of some religious articles that are currently derogated from the restriction:

- Icons;
- Crucifixes; and
- Rosaries.

No further details or descriptions were provided on these articles in the guideline document. It is assumed that lead is present in most religious articles that contain crystal glass, enamels and precious and semi-precious stones, to obtain the visual properties that the market is accustomed to. There is a lack of evidence on the typical concentrations of lead within religious articles or how many of these religious articles are made or sold within the EU, so it is not possible to estimate with any confidence how many (or, which types of) articles would fall within the scope of the restriction.

4.2.3. Assessment of alternatives

As mentioned in Section 4.1, the Annex XV restriction proposal did not include an assessment of alternatives to lead in religious articles. In the absence of further information from the call for evidence and stakeholder follow-ups, it has not been possible to provide any new information on possible alternative materials to lead in crystal glass, enamels and precious and semi-precious stones.

4.2.4. Removing derogation scenario

Under this scenario, the existing derogation set out in paragraph 8(i) of the Annex XVII entry 63 would be removed after a transition period (yet to be defined). This means that after this transition period:

- Religious articles shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0.05 % by weight, and those articles or accessible parts thereof may, during normal to reasonably foreseeable conditions of use, be placed in the mouth by children.
- Religious articles may continue to be placed on the market or used in articles supplied to the general public where it can be demonstrated that the rate of lead release from such

²⁸ https://echa.europa.eu/documents/10162/13563/lead_guideline_information_en.pdf

an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0.05 µg/cm² per hour (equivalent to 0.05 µg/g/h). In addition, for coated articles, it should be demonstrated and, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article.

Removing the existing derogation could potentially impact companies sourcing materials, companies manufacturing and distributing religious articles, and the end-users / customers. However, the fact that no information on such impacts was submitted in the call for evidence may imply that the restriction does not cause any substantial, adverse impacts on the industry, or that relevant companies producing religious articles may not be aware of ECHA's call for evidence.

4.2.4.1. Most likely response to removing derogation

Manufacturers of religious articles would have the following general options:

- Switch to manufacturing using an alternative (lead-free) material;
- Continue production for the non-EU market only;
- Cease production in the EU and relocate outside the EU to continue to supply the non-EU market; or
- Cease production in the EU but not relocate.

Assuming that demand for religious articles is linked to its religious value rather than aesthetic properties (e.g. colour and brightness), one can infer that manufactures will look to their suppliers for alternative materials to continue to make religious articles without lead.

4.2.4.2. Cost of removing the derogation

Due to the lack of stakeholder input, there is no new information on the socioeconomic impacts of removing the derogation for religious articles. As mentioned in Section 3.3.4., this lack of engagement may indicate that the manufacturers of religious articles are not significantly impacted by the proposed restriction or the lack of engagement may be due to the issue that ECHA's call for evidence has not reached the relevant companies.

4.3. Conclusions

The Annex XV restriction proposal did not include an assessment of alternatives to lead in religious articles. In the absence of further information from the call for evidence and stakeholder follow-ups, it has not been possible to provide any new information on possible alternative materials to lead in religious articles. The lack of engagement during the call for evidence may indicate that the manufacturers of religious articles are not significantly impacted by the proposed restriction or that many companies were not aware of the call for evidence.

During the call for evidence no evidence was submitted that would confirm nor contradict the findings of RAC/SEAC as per their opinion.

In the absence of new information on possible alternative materials to lead in religious articles and on the impact of restricting lead in those articles, ECHA is not in a position to advice the Commission whether to continue exempting religious articles or not.

5. Portable zinc-carbon batteries and button cell batteries

5.1. Rationale for the derogation

Portable zinc-carbon batteries and button cell batteries were exempted from the restriction at a later stage of the process and hence there is no information in the Background Document justifying this exemption. Instead, these batteries (referred to as certain batteries) were mentioned in the Commission Regulation (EU) No. 2015/628 and derogated on the same basis as religious articles.

5.2. Information received

5.2.1. Quantity and technical function

According to Handelsverband Deutschland, a retail trade association and KiK Textilien und Non-Food GmbH, a large textile company, lead is intentionally added to zinc carbon batteries to create a zinc-lead alloy. This is done for several reasons:

- Lead is added to zinc to reduce the tendency for hydrogen formation from the electrolyte at the electrode – this is why lead is sometimes referred to as an anti-gassing agent.
- Lead increases the corrosion resistance of the battery from the electrode and improves the mechanical properties of the zinc alloy.
- The addition of lead substantially improves the processing of the battery, making it far easier to recycle.
- All in all, this leads to a higher product safety because the risk of the battery bursting or leaking is significantly reduced.

It should be noted that the lead content in zinc-carbon batteries has steadily declined over long periods of time and is now at an all-time low.

According to the European Portable Battery Association lead concentrations in portable zinc-carbon batteries vary from higher levels of 1 000/2 000 mg/kg²⁹, to lower levels 40/50 mg/kg.

In the absence of further information, it is assumed that lead has the same function in button cell batteries. While no stakeholders provided information on the concentration of lead in button cell batteries, the heavy metal content (lead, mercury and cadmium) of household batteries has been assessed by Recknagel and Radant (2013)³⁰. The lead content varies depending on the different battery types. The batteries that were analysed came from different producers and were bought in Germany and for each battery type two specimen were investigated, amounting for the button cell and zinc-carbon batteries to a test sample of 210 pieces. The batteries for the study were purchased by retail, by mail order or on flea markets. The findings of the study with regard to lead content in zinc-carbon and button cell batteries are illustrated in Table 8 below.

²⁹ 1 000 mg/kg is the same as 1 000 parts per million (ppm).

³⁰ Recknagel & Radant (2013)

Table 8. Lead content in different battery types, tests conducted in 2011 (Source: Recknagel & Radant 2013)

Battery type	Number of tested batteries types	Pb content range mg/kg
Zinc–air button cells	30	14 - 509
Alkaline/manganese button cells	24	6 - 486
Silver oxide button cells	15	< 1 - 44
Zinc/carbon mono-cells	25	178 – 1 958
9V zinc/carbon batteries	11	535 – 1 103

From Table 8 it is evident that button cell batteries comply with limit of lead content of 0.05 % by weight of the article, while the limit is exceeded by the zinc-carbon batteries. This is further supported by a confidential report submitted by Tukes, Finland on the test of a button cell batteries, where test results indicate lead content of 0.01 %.

5.2.2. Market for portable zinc-carbon and button cell batteries

Button cell or coin batteries are named due to their thin, cylindrical shape. These cells come in several diameters and widths although almost all of them utilise lithium-ion or alkaline chemistries. Due to their differing shapes and performances, different button cells have different (but specific) uses; common articles that require button cells are³¹:

- Watches (wrist-watches)
- Cameras
- Calculators
- Some toys (miniature electronic devices, e.g. interactive children's books)
- Car keys / keyless entry key fobs for cars
- Laser pointers
- Some medical testing devices

Wagner (2014) revealed that up until the late 1950s, portable zinc carbon batteries were the primary battery cells. However, in 1959, Eveready managed to reduce the high price tag of alkaline batteries inventing a new alkaline battery that consisted of (alkaline electrolyte with) a manganese dioxide electrode (cathode) and a powdered zinc electrode (anode). These alkaline batteries accounted for 80 % of the over ten billion battery units that were produced worldwide in 2011. This trend (of zinc-carbon batteries becoming less common) has continued with modern electronic articles requiring higher performances from batteries that zinc carbon batteries cannot reach.

The declining market share was reiterated by Handelsverband Deutschland and KiK Textilien

³¹ <https://www.panasonic-batteries.com/en/specialty/lithium-coin/coin-lithium-cr1216>

und Non-Food GmbH who noted that the market share of zinc-carbon batteries has been steadily decreasing for years. This trend is accelerated by old devices with low technical requirements being replaced by modern articles requiring both higher battery capacities and higher peak currents, which zinc-carbon batteries cannot provide.

Thus, they conclude that zinc-carbon batteries, which are already a niche product, are likely to be used less and less in the near future. The European Portable Battery Association commented that zinc-carbon batteries represent approximately 10 % of the market, and button cell batteries represent approximately 8 % of the total EU battery market.

Japan Electronics and Information Technology Industries Association explained in the call for evidence that batteries containing more than 0.004 %/weight lead, has a Pb symbol displayed on the product as required by EU battery regulation. Therefore, these batteries are easily identifiable on the market, and they believe that there are few batteries on the market that needs this product labelling (have over 0.004 %/weight lead). This was also confirmed by large companies such as Panasonic who have not sold zinc-carbon batteries that contain lead since 2012.

However, as demonstrated by a Member State Authority (Germany) - during the recent call for evidence a study conducted by UBA (2013) into heavy metal contents in portable batteries showed that there was noticeable lead content in the zinc-carbon batteries tested. The zinc carbon round cells and zinc-carbon volt-blocks tested exhibited significantly higher lead contents (178 – 1958 mg lead per kg and 535 – 1103 mg/kg, respectively), compared to aluminium-manganese (AlMn) round cells that only contained 1.3 – 12.8 mg/kg of lead. The cadmium and mercury contents in the investigated AlMn round cells was also found to be lower than that in the zinc carbon round cells. Therefore, it is assumed that the remaining lead-containing zinc carbon batteries on the European market contain more lead than AlMn, or alkaline alternatives.

5.2.3. Assessment of alternatives

There is a range of potential alternatives to lead-containing zinc carbon batteries. The following are three primary alternatives which are all already available on the European market:

- Alternative elements - cadmium, mercury or manganese;
- 'No replacement' - lead-free zinc carbon batteries; and
- Alternative battery systems / chemistries e.g. alkaline or lithium-ion batteries.

Alternative elements

Handelsverband Deutschland and KiK Textilien and Non-Food GmbH informed that the most common alternative elements are cadmium and mercury. However, these pose a significantly higher risk to the environment and to humans and, as noted by the European Portable Battery Association, would lead to concerns with REACH regulation. These elements are therefore considered unsuitable alternatives from a human health and environmental risk perspective. Manganese has historically been tested as a substitute, but the addition of manganese leads to a much more brittle and generally less resilient alloy – this means that the lifespan of the battery decreases. A reduced lifespan, would result in higher risks for the consumer because of risks of leakage. Therefore, manganese is not considered a technically feasible alternative.

Lead-free zinc-carbon batteries

According to Handelsverband Deutschland and KiK Textilien und Non-Food GmbH lead-free zinc-carbon batteries are more brittle and generally less resilient compared to lead-containing zinc-carbon batteries. For this reason, it is said that lead-free zinc-carbon batteries do not appear in the market in significant numbers. They also comment that lead content in zinc-carbon batteries is at an all-time low, and that environmental protection is guaranteed by well-established recycling schemes. However, as mentioned in Section 3.4.2., large portable battery manufacturers such as Panasonic only sell lead-free zinc-carbon batteries, therefore, these alternatives may be more readily available than indicated by some stakeholders.

Alternative battery systems / chemistries

A Member State Authority (Germany) - commented during the call for evidence stating that zinc-carbon batteries could be replaced by other chemical battery systems / chemistries, in particular alkaline-manganese or nickel-metal hydride batteries, which are already available on the market. These alternatives also offer performance advantages in terms of storage capacity, service life and temperature sensitivity. Although these are technically feasible alternatives, these batteries are more expensive to consumers. When these alternative batteries are used for simple devices, the extra benefits (in terms of higher capacity, higher ampage, etc.) may not be noticeable for the consumers compared to the cheaper zinc-carbon batteries. This notwithstanding, EUROBAT (2019) revealed that lithium-ion batteries (introduced by Sony in 1991) are dominating the current European portable battery market due to the high capacity of the chemicals used and the ability for the batteries to be recharged. Therefore, it seems likely that this alternative technology will continue to replace lead-containing zinc carbon batteries over time.

5.2.4. Removing derogation scenario

Under this scenario, the existing derogation set out in paragraph 8(j) of the Annex XVII entry 63 would be removed after a transition period (yet to be defined). This would mean that after this transition period:

- Portable zinc-carbon batteries and button cell batteries shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0.05 % by weight, and those articles or accessible parts thereof may, during normal to reasonably foreseeable conditions of use, be placed in the mouth by children.
- Portable zinc-carbon and button cell batteries may continue to be placed on the market or used in articles supplied to the general public where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0.05 µg/cm² per hour (equivalent to 0.05 µg/g/h). In addition, for coated articles, it should be demonstrated that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article.

5.2.4.1. Actors affected

The European Portable Battery Association suggested that the entire portable battery supply chain from manufacturers, freight forwarders, distributors and customers / end-users would be impacted by the removal of this derogation. However, as there are unlikely to be manufacturers or distributors that solely produce / sell portable zinc-carbon or button cell

batteries, the restriction should not apply overwhelming pressure to the battery industry, as the stakeholders will already be producing lead-free zinc-carbon batteries or batteries based on alternative chemistries. Thus, a redistribution of sales from lead-containing to lead-free and other alternative batteries will likely occur.

5.2.4.2. Most likely response to removing derogation

Manufacturers

Manufacturers of portable zinc-carbon batteries and button cell batteries would have the following options:

- Replace lead in batteries with an alternative element;
- Remove the lead in batteries and produce lead-free batteries;
- Continue production for the non-EU market only;
- Relocate production of lead-containing batteries outside the EU to continue to supply the non-EU market; or,
- Cease all lead-containing production without increasing production of alternative batteries.

Portable zinc-carbon batteries are mostly used for low performance, high lifespan articles such as television remote controls or clocks. Already available alternatives have benefited from further technological advancement and the increase in newer article's performance requirements has already started to lead to phase-out zinc-carbon batteries. The European Portable Battery Association suggests that removing the derogation would most likely stop (lead-containing) zinc-carbon batteries being manufactured.

Consumers

Handelsverband Deutschland and KiK Textilien und Non-Food GmbH suggested that if zinc-carbon batteries were no longer covered by a derogation, the restriction would negatively impact consumers. The stakeholders' view was that a large proportion of customers would not switch to more expensive batteries because they would not see any benefit in it. However, as discussed below in Section 5.2.4.3., the increase in costs to the consumers is marginal, implying that the consumers would not be heavily affected. As the current European market situation stands, it is likely that lead-containing zinc-carbon batteries will continue to be phased out over time, which means that the removal of the derogation would simply lead to earlier replacement in the remaining applications of these batteries.

Some respondents have indicated that some consumers might 'self-import' zinc-carbon batteries that contain lead that are manufactured in countries outside of the EU-28. This is an enforcement issue and is therefore not included in the potential outcomes from removing the derogation for portable zinc-carbon batteries and button cell batteries as it is assumed that consumers in the EU will not be able to illegally import batteries whilst living in the EU.

5.2.4.3. Economic costs of removing derogation

Since it is likely that most companies supplying portable zinc-carbon batteries and button cell batteries will also supply their alternatives, other than some distribution impacts (increased sales for one type of battery with reduced sales for another type of battery), the main impact of removing the derogation would appear to be the higher *initial* cost to consumers which are discussed below. This does not necessarily result in a higher total cost to consumers as

alternative batteries have better product performance.

Handelsverband Deutschland – a trade association - submitted evidence in the call for evidence indicating that portable zinc-carbon batteries are generally the cheapest alternative for the consumer. In comparison, alkaline batteries of comparable size and capacity are on average twice as expensive. Based on data from their member companies, the total financial cost for the customer was estimated to around €15 million/year, if zinc-carbon batteries were discontinued. KiK Textilien und Non-Food GmbH presented the same price difference between a zinc-carbon battery and an alkaline battery (100 % more expensive), as Handelsverband Deutschland, and estimated that a removal of the derogation would induce socio-economic costs of approximately €13.5 million to the portable battery market and approximately €3 million to the company itself.

The European Portable Battery Association stated that if the derogation for portable zinc-carbon batteries and button cell batteries is removed, they expect production of zinc-carbon batteries to stop. They presented substantially higher cost estimates in the region of the €10–€100 million. They also believe that removing of the derogation would affect not just day-to-day users, but medical and military uses as well.

Information gathered from a simple desk-based internet search of well-known manufacturers of portable batteries revealed that AA zinc-carbon batteries (whether they contain lead or not) are the cheapest options and cost between €0.10 – €0.60 per battery³². However, lead-free AA batteries are predominantly alkaline based and cost approximately €0.30 – €1.20 per battery³³. This is reflective of the above stakeholders' estimations that alternatives to portable zinc-carbon batteries are approximately 100 % more expensive. Despite a large relative difference, the absolute price difference is low - in the range of €0.50 – €1.00 per battery.

Whilst the consumer or household may incur higher initial purchase costs, these are deemed affordable and may not necessarily result in higher total costs over time. Energy consumption has changed in some devices that historically used zinc-carbon batteries (e.g. simple door bells are being replaced with cameras/videos that connect with smart phone technology and TV remotes are more heavily used with more interactive TVs), whereby zinc-carbon batteries may not be suitable for these devices or that higher performing batteries may be more cost effective for the consumer. The same concept can also be said with button cell batteries (e.g. fitness trackers and watches) which may require a higher performance battery compared to traditional electronic watches.

As explained above, the lead-containing zinc-carbon batteries are already 'naturally' being phased out, any direct economic costs incurred by the consumers would decrease over time. For example, today's market may indicate a total cost increase of €15 million/year, but the market in five years may only imply €5 million/year if there is a strong declining market trend. Taking into account the decreasing market for lead-containing zinc-carbon batteries as well as the added benefits (performance and lifetime) of the alternatives, the total costs of

³² <https://www.batterystation.co.uk/brands/panasonic-batteries/panasonic-zinc-carbon-batteries.html> and <https://www.amazon.com/s?k=zinc+carbon+aa+battery>

³³ <https://www.duracell.co.uk/products/alkaline-batteries/?size=aa#our-products> and https://www.batterystation.co.uk/battery-types/aa-batteries.html?bc_fsnf=1&Battery+Technology=Alkaline

removing the derogation are likely to be moderate.

5.3. Conclusions

The three primary alternatives already available on the EU market and their suitability and availability are briefly described below:

- *Some alternative materials* are not considered as suitable or desirable. The most common alternative materials for this use (cadmium and mercury), pose significant risks to the environment and humans and would lead to concerns with REACH Regulation, substituting lead with manganese decreases the lifespan of the battery due to much more brittle and generally less resilient alloy and increases the risk of leakage.
- *Lead-free zinc-carbon batteries* are more brittle and generally less resilient compared to lead-containing zinc-carbon batteries. While lead-free zinc-carbon batteries are already available on the market, some stakeholders underlined that they do not appear in significant quantities. Nevertheless, these alternatives may be more readily available than indicated as large portable batteries manufacturers, such as Panasonic only sell lead-free zinc-carbon batteries (Section 5.2.2).
- *Alternative battery systems / chemistries*, such as alkaline-manganese or nickel-metal hydride batteries are a possible substitute for zinc-carbon batteries and are already available on the market. Furthermore, lithium-ion batteries (introduced by Sony in 1991) are dominating the current European portable battery market due to the high capacity of the chemicals used and the ability for the batteries to be recharged.

As illustrated in table 8, the zinc-carbon round cells and zinc-carbon volt-blocks have a lead content in the range of 178 – 1958 mg lead per kg and 535 – 1103 mg lead per kg, respectively, thus exceeding the limit of 0.05 % by weight of the article. Based on the information gathered during the call for evidence and the contract with Eftec, it is evident that the market share of zinc-carbon batteries has been steadily decreasing over the years due to the switch from old devices with low technical requirements to modern articles requiring both higher battery capacities and higher peak currents. Zinc-carbon batteries represent approximately 10 % of the market and their share is expected to further decrease over time. Removal of the derogation is not expected to pose significant costs to consumers. While alternatives to zinc-carbon batteries (e.g. alkaline batteries) are 100 % more expensive, the absolute price difference for consumers is low - in the range of €0.50 – €1.00 per battery.

Button cell batteries represent approximately 8 % of the market. Based on the evidence gathered during the call for evidence and following up on key stakeholders, it could be concluded that the lead content of button cell batteries is within the limit. The information on the ranges of lead content summarised in Table 8 indicates that the lead content in all button cell battery types, including zinc-air button cells, alkaline/manganese button cells and silver oxide button cells, is less than 0.05 % of the weight of the article. This is further supported by a confidential report submitted by Tukes, Finland on the test of a button cell batteries, where test results indicate lead content of 0.01 %.

6. Availability of lead migration testing methods and their ability to meet the requirements in the legislation

Following the request of the Commission, ECHA assessed:

- Availability and suitability of analytical methods to determine that the rate of lead release from articles (coated or uncoated) does not exceed the limit of 0.05 micrograms/cm² per hour.
- that the coatings mentioned in paragraph 7 are sufficient to ensure that the release rate of lead is not exceeded for a period of at least two years of normal and reasonably foreseeable conditions of use of the article.
- the suitability of the wear test method EN 12472:2005+A1:2009, as well as the availability of other methods, to determine coating integrity of articles containing lead should be subjected to expert assessment.

ECHA has gathered information through a call for evidence³⁴, from targeted literature review and targeted survey with Forum Members and where relevant, interviews with experts (among which a member of the relevant CEN working group, TÜV Rheinland and the Assay Office) to assess the availability of lead migration methods for coated or non-coated consumer articles and their enforceability.

6.1. Hazard/exposure/emissions and risk

In the Background document to the Opinion on the Annex XV dossier proposing restrictions on Lead and its compounds in articles intended for consumer use (2014), the unacceptable risk of lead exposure from food and non-food sources leading to severe and irreversible effects on children's health are described. Ingestion and mouthing of items was recognised as the most important route to unintentional exposure of lead and its compounds in children. In the Background Document an oral exposure scenario from repeated chronic exposure from mouthing lead containing items (such as a button, zipper flap, print on clothing etc.) was described. For the assessment of this potential exposure, the following information and assumptions were used:

1. The sensitive subpopulation is neurologically still developing, small children likely to mouth items.
2. The daily mouthing time for different types of consumer products has been based on three published studies.
3. Information on lead content in different consumer products (e.g. key rings, buttons, zippers, pens, bags, wallets and raingear) comes from analyses performed by the Swedish CA and other published data on the occurrence of lead in consumer products.
4. A migration rate of 0.7 µg/h/cm² /(% lead in product), based on an assessment taken from the migration data presented by the Danish EPA survey (2008) and re-evaluated by RAC for the Background Document to RAC and SEAC opinions on lead and its compounds in jewellery (2011).

³⁴ <https://echa.europa.eu/calls-for-comments-and-evidence/-/substance-rev/23601/term>

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In the Danish EPA survey (2008), a clear linear trend correlates lead content and migration at the highest lead content for the metallic parts of jewellery. The RAC conclusions from this report indicated a good correlation between migrations based on surface. Even though the available information on migration rates at low lead concentrations had a lower accuracy level, RAC decided to use the migration rate of $0.7 \mu\text{g}/\text{h}/\text{cm}^2 /(\% \text{ lead in product})$ for the exposure assessment. RAC also concluded that in the absence of data the same association could be used for non-metallic parts and therefore the same concentration limit could be used to ensure the same level of protection.

Children suck and chew on non-food items, toys and childcare articles 15-20 minutes a day (ECHA 2014). A lead threshold value of 0.05 % lead in consumer articles (that can be mouthed by small children) was set and supported by the tolerable lead content in consumer articles calculated in the Background Document. Furthermore, as reported in the Background Document (ECHA 2014) the restriction is based on toxicity data and the exposure assessment reported in the proposal.

In their evaluation of the restriction proposal on lead in consumer articles, RAC, as described in their opinion, decided that as some materials have low migration levels, industries may be allowed to place on the market articles exceeding the concentration limit of 0.05 % lead provided that the actual migration does not exceed the proposed migration limit of $0.05 \mu\text{g}/\text{cm}^2$ per hour ($0.05 \mu\text{g}/\text{g}$ per hour).

SEAC supported RAC's approach and recommended that the restriction should be based on content (w/w), with an option for industries to demonstrate, using appropriate justification, that due to a low migration a particular article can be placed on the market. This was further supported by industries as migration limits will allow market operators to avoid re-engineering costs when lead is present in their articles in concentrations higher than 0.05 % but where the migration rates are within the limit.

Therefore, according to paragraph 7 of entry 63 of Annex XVII to REACH, the restriction holds a dual condition: 1) concentration of lead (expressed as metal) in concerned articles or their accessible parts should be equal to or greater than 0.05 % by weight, and those articles or accessible parts may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children; the restriction however *shall not apply* where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed $0.05 \mu\text{g}/\text{cm}^2$ per hour (equivalent to $0.05 \mu\text{g}/\text{g}/\text{h}$), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article.

For coated items, any coating would have to be substantial enough to last for a reasonable length of time to be effective in preventing migration of lead if it was mouthed. It was therefore proposed to add a similar condition to that used in the restriction on nickel (entry 27(1)(c))³⁵. The Compendium of analytical methods Recommended by the Forum to check compliance with Reach Annex XVII restrictions³⁶ recommends the EN 12472:2005+A1:2009 for entry 27(1)(c), which is a method for the simulation of wear and corrosion for the detection

³⁵ <https://echa.europa.eu/documents/10162/7851171d-53e9-455a-8bb8-7ca22e89ad87>

³⁶ https://echa.europa.eu/documents/10162/13577/compendium_of_analytical_methods_en.pdf

of nickel release from coated items.

6.2. Approach for evaluating suitability, availability and enforceability of the methods

To provide an assessment of the available testing methods' suitability to determine that the rate of lead release from articles (coated or uncoated) does not exceed the limit of 0.05 µg/cm² per hour, a conceptual level approach of test accuracy was taken with sufficient scope to discuss the identified key aspects of the methods³⁷. Therefore, for both the migration and the wear and corrosion testing, we identified two aspects of assessment in which the accuracy of the testing method can be controlled for the benefit of enforceability and suitability;

- 1) the trueness of the method
- 2) the precision of the method, which can be further subdivided to the ability to an individual testing entity to gain repetitious testing results within acceptable margins of error (i.e. repeatability) and the ability of a number of individual testing entities to gain comparable testing results between the testing entities (i.e. reproducibility)

The trueness of a method may be reduced in the case of a systematic error, e.g. if the testing is not able to capture the range of lead migration by mouthing in a representative way. Differences in repeatability and reproducibility create variability within the captured reference range of lead migration. Furthermore, the specific objective of this entry need to be kept in mind; the provision of a sufficient level of protection to children from lead exposure. With this in mind the ultimate aim of the method should be the avoidance of *false positives*; the placing in the market of articles that positively tested for compliance but are in fact not compliant. The conceptual level approach taken for evaluating method accuracy is discussed in 7.2.3.

The lack of specific suitable testing methods for lead migration facilitated by mouthing was discussed in the Background Document to the opinions on the Annex XV dossier (ECHA 2014). The most discussed aspect in relation to the need to develop such methods was the composition of simulant fluid i.e. artificial saliva used in the testing and its appropriateness to the specific testing need in question.

Therefore, this investigation conducted by ECHA in evaluation of available testing methods for lead migration testing gave special importance on evaluating this aspect. Furthermore, other relevant factors were identified on the basis of the information from RAC and SEAC opinions, targeted literature search and discussions with experts as follows:

- Composition of the artificial saliva (salts, enzymes, acids etc.)
- pH and temperature
- Testing duration
- Presence of agitation
- Determining and processing of the test piece
- Other process-related issues

³⁷ Evaluation of accuracy is a part of an analytical method validation which in practice is a complex expert field see e.g. <https://www.sciencedirect.com/science/article/pii/S0165993607000118>

The details of the migration testing investigation are discussed in 6.2.1. For coated articles, the investigation concentrated on assessing the suitability of EN 12472:2005+A1:2009 for the simulation of wear and corrosion for the detection of lead release from lead containing coated items. As the method is a practical solution for simulating wear and corrosion for nickel containing articles, experiences from the nickel testing were also seen as relevant within the scope of the investigation. The investigation for corrosion and wear testing is presented in 6.2.2.

To support the approach taken to evaluate the testing methods in 6.2.3, ECHA also gathered general information and experiences of companies and other interested stakeholders through a call for evidence and organised a targeted survey for the members of the Forum. Furthermore, expert views in appropriate scientific or practical fields were acquired where necessary. The overview of the results from these consultations is provided in section 6.3. The conclusions from evaluating the methods together with the provided feedback are discussed in 6.4.

6.2.1. Test methods for corrosion and wear

For coated consumer articles, the potential risk of lead exposure depends on the effectiveness of the coating in preventing migration of lead. A practical solution to assess the effectiveness of the coatings is to test their endurance to corrosion and wear. In the Background Document to the opinions on the Annex XV dossier it was stated that for coated items, the coating should be sufficient to ensure that the rate of lead migration from any mouthed parts will not exceed the relevant limit for a period of at least 2 years of normal or reasonably foreseeable conditions of use of the article (ECHA 2014).

Standard EN 12474 (1998) was developed for the Nickel directive, revised by CEN (2005) and further amended in 2008³⁸. The standard introduces a pragmatic solution to simulate wear and corrosion of a coated article during two years of normal use. The testing method is to be used prior to the testing of nickel release³⁹ from coated articles that come into direct and prolonged contact with the skin. From the article itself, a relevant test part may be dismantled and/or cut to be tested further. In practice, the testing contains three stages; exposure to corrosive atmosphere, wear simulation within a tumbling barrel containing wear medium and abrasive paste and finally, the testing of the metal migration with the applicable European standard. The first stage of the test aims to simulate accelerated corrosion by sweat with suspension containing a mixture of lactic acid and sodium chloride, covering the parts of the article that would be in contact with skin. The article is kept in suspension for 2 hours in 50 °C. The wear stage follows with 5 hour rotation in the tumbling barrel with the wear medium. The test is performed twice: once to ensure the coating does not contain any of the tested contaminant and a second time to test the normal scenario. For lead this can be done as well, in case e.g. there is a pigment in the paint applied to the article. The size limit of articles is determined by the size of the tumbler (80 cm diameter).

The 2005 revision of the Nickel standard enabled testing of spectacle frames due to changes in the tumbling equipment and wear medium. In addition, the testing time was set to 5 hours

³⁸ 2018 revised version under review

³⁹ EN 1811, Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin

instead of 2 and the test articles were to be attached to a retaining structure instead of being placed in the wear medium directly (Baker 2018). According to Baker (2018) in the last published revision in 2008, the method of preparation of the wear medium was changed.

In practice, the conditions of wear for any individual article may vary greatly. The approach of EN 12472 is of pragmatic nature due to the likely undefinable variation in wear and corrosion for a wide range of articles in wide situations of use. However, as the method precedes EN 1811 it has been relevant for it to simulate direct and prolonged contact with the skin and therefore, the effect of corrosion by simulated sweat. This may be relevant with a range of consumer articles as well but for some articles is not likely that skin contact and sweat have an essential role in terms of corrosion during the articles life time⁴⁰.

6.2.2. Lead migration testing methods and requirements

Lead migration testing aims to mimic the real life situations under which lead is mobilized from the matrix and becomes bioaccessible. Within the context of entry 63 of REACH article XVII migration tests aims to measure the bioaccessible fraction of lead, the maximum amount of contaminant available for absorption. The determination of the bioaccessible fraction of a contaminant include three basic stages: the determination of the article - whether whole, cut or dismantled piece - to be tested and their surface areas, followed with lead migration testing in artificial saliva and finally the measurement of the migrated lead fraction from the testing liquid⁴¹.

Lead migration testing provides a measure of the mass of chemical from an article into artificial saliva over time by placing the article into a simulated digestive liquid; the fraction of the contaminant mobilized to the liquid is defined as the bioaccessible fraction, representing the maximum amount of contaminant available for absorption⁴² (Van Engelen et al./RIVM 2008).

The EN 71-3 (Table 9) standard applied in the Toy Safety Directive was suggested as an option by RAC to start developing test methods for migration- although it was recognised as an approach that could potentially lead to overestimation in comparison to less acidic artificial saliva testing (ECHA 2014).

A key parameter in migration testing is the composition of the simulated digestive liquid, this was clearly recognised in the Background Document (2014). As argued by Weidenheimer et al. (2011) the use of hydrochloric acid (HCl) in gastro-intestinal testing mimics more the

⁴⁰ The Guideline on the scope of the amendment of Entry 63 of Annex XVII to REACH on: Lead and its compounds in articles supplied to the general public that can be mouthed by children includes e.g. decorative magnets, rubber erasers and Christmas decorations in the scope: <https://echa.europa.eu/documents/10162/a55e40f4-9515-475a-a6de-25bd991c3f84>

⁴¹The total content of migrated contaminant in the testing fluid can be measured by several instruments used to measure metals in solutions such as inductively coupled plasma mass spectrometry (ICP - MS), inductively coupled plasma optical emission spectrometry (ICP - OES) and graphite atomic absorption spectrometry (GF - AAS).

⁴² Three major processes of oral bioavailability were set out by RIVM, including F_B as the bioaccessible fraction, F_A as the amount of F_B that is transported from the lumen across the intestinal epithelium and into the portal vein of the lymph and thirdly F_H , representing the unmetabolized fraction transported from the liver to the systemic circulation.

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scenario where an item is ingested rather than just mouthed⁴³. The gastro-intestinal testing approach that has been utilised in EN 71-3 relies on a more corrosive, acidic approach, leading to an overestimation of exposure. Therefore a less acidic saliva simulation is considered more appropriate when assessing the lead migration as a result of mouthing of an item. Also, according to the Background Document EN, 71-3 tests parts fitting into a “small parts cylinder” which is likely not possible with items big enough sized to be only mouthed, not ingested. Changing the size of the cylinder has implications to the amount of testing solution as well.

According to the Background Document to the opinions on the Annex XV dossier, another test method that was considered in the German national standard DIN 54233-4, which forms the basis of the Oeko-Tex 100⁴⁴ standard for voluntary chemical control in textiles (ECHA 2014). This standard describes a synthetic salivary solution used for extraction of lead and other metals. This standard been qualified by comparison to other analytical standards, and according to the Background Document could well be integrated into the EN 71-3 framework. However, the artificial saliva in DIN 54233-4 contains, just like EN 71-3, a more acidic pH than actual saliva⁴⁵ (Table 9).

In addition to DIN 54233-4 and EN 71-3, other testing methods, such as Health Canada C.08 and C.10, US CPSC (3) and EN 1388-1 were also briefly discussed in the opinions of RAC and SEAC (ECHA 2014, Table 9). These tests were seen to be proven useful both for enforcement authorities and for internal control carried out by market actors in within the framework of legislation under which they are recommended⁴⁶, however a similar concern of the composition of the extraction liquid was raised by RAC due to the weakly acidic extraction fluid (ECHA 2014).

On the basis of the considerations above, RAC suggested to take DIN 54233-4 and EN 71-3 as a base for the development of new testing method with some necessary alterations to both. In relation to the EN 71-3 standard, it was seen that similar to articles targeted with entry 63 of REACH article XVII, toys can be made out of variety of different materials and designs and this similarity was seen as a further benefit if EN 71-3 would serve as a starting point for a new standard (ECHA 2014).

The exact contents of the artificial saliva and other testing conditions, such as the need for mouthing-simulating agitation or the appropriate pH and temperature affecting the end-result of mouthing induced chemical migration, have been discussed in the scientific literature. There are variations in the artificial saliva compositions, some consisting of e.g. urea and lactic acid (Ionas et al. 2016), mucin (Versantvoort et al. 2005), and alpha-amylase (Versantvoort et al. 2005, Marques et al. 2011) in various concentrations. Thus it can be concluded that different methods and extraction mediums may give results that do not represent the exposure correctly.

⁴³ This approach has been taken for example in testing the safety of toys and migration of certain elements in EN 71-3.

⁴⁴ https://www.oeko-tex.com/importedmedia/downloadfiles/STANDARD_100_by_OEKO-TEX_R_-_Standard_en.pdf

⁴⁵ The Background document also noted that DIN 54233-4 is a national standard which is also at hand only as a draft, which calls for more standardisation work to be carried out at European level.

⁴⁶ The resemblance among the methods can be viewed as an indicator of their effectiveness and practical workability (Background document 2014).

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The US Environmental Protection Agency (US EPA) recently recommended that the artificial saliva is prepared at physiologically relevant temperature and pH and containing also relevant enzymes and salts in concentrations likely to be present in the mouth⁴⁷ (US EPA 2017) when testing with contaminants for the potential to leach or migrate, regardless of the actual substance in questions.

The Joint Research Centre (JRC) has conducted scoping investigations on the release of metals from the rim area of decorated articles including method EN 13811-1. Even though lead exposure from the rim area is due to lip contact, it is facilitated via acidic food material and not saliva⁴⁸. Therefore the method is not applicable to test migration from mouthing.

The *in vivo*-validated Unified BARGE *in vitro*-method (UBM) has been developed by the Bioaccessibility Research Group of Europe⁴⁹ to measure the bioaccessibility of soil contaminants. The method simulates human gastro - intestinal tract through 3 different compartments: mouth, stomach and small intestine with four digestive fluids, including physiologically based artificial saliva with organic components. According to the developers The UBM has been used to look at the solubility of various metals from food, toys and jewellery.⁵⁰ The agitation phase of UBM does not resemble prolonged mouthing-only situation but is rather a representation of mouthing and chewing before ingestion, which can be considered to last for a relatively short period of time. Therefore the mouthing phase in the UBM method lasts for seconds to minutes. The UBM has been standardized in ISO 17924:2018 (Table 9).

The migration protocol by Urrestarazu et al. (2014) applies an artificial saliva solution containing mucus (Table 9). During the development of the original restriction proposal, the European Copper Institute provided results from the protocol for assessment (ECHA 2014). It was used in testing of different lead containing brasses but also other alloys such as lead containing nickel silver. The results indicated, that the lead migration rate in saliva might exceed 0,05 µg Pb/cm²/h when the content of lead in the alloy is above 0.5 %. RAC recommended a derogation for brass alloys in articles up to 0.5 % of content due to the results reported by the ECI.

⁴⁷

https://www.epa.gov/sites/production/files/201801/documents/indoor_exposure_testing_protocols_version_2.pdf

⁴⁸ Personal communication with JRC expert

⁴⁹ <https://www.bgs.ac.uk/barge/home.html>

⁵⁰ Personal communication with Dr's Mark Cave (Chairman of BARGE) and Joanna Wragg (Secretary of BARGE)

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Table 9. Methods for lead migration analysis

Testing method	EN 71-3	EN 16711-3	DIN 54233-4	EN 1388-1*	C.08	C.10	US CPSC (3)	ISO 17924:2018	Protocol by Urrestarazu et al. 2014
Scope	Toys	Textiles (suitable for all consumer articles)	Textiles	Ceramic wear in contact with foodstuffs	Consumer products	Ceramics and glassware in contact with foodstuffs and lip and rim	Jewellery	Metals in soil	Copper and tin alloys
Suitable for mouthing scenario	No (for ingestion scenario only)	Yes	Yes	No (for ingestion scenario only)	No (for ingestion scenario only)	lip and rim	Yes	Yes	Yes
Sample size	Fitting to "small parts cylinder"	According to EN 1811	1 cm ²	Distinction between flat and shallow dish	Fitting to "small parts cylinder"	Distinction between different dish designs	N.A.	N.A.	Discs in diameters of 3.9 - 4.85 cm
Testing fluid	0.07 M HCl	Artificial saliva solution	Artificial saliva solution	0.07 M HaC	0.07 M HCl	4% Hac	0.07 HCl	Physiologically based artificial saliva	150 mM NaCl, 0.16% porcine Mucin and 5 mM buffer MOPS
Presence of agitation	Shaker 100 RPM	Shaker 60 RPM	Yes	N.A.	N.A.	N.A.	N.A.	Manual shaking	Shaker 60 RPM
pH and temperature	1.2 pH/37 °C	6.8 pH/40°C	2.5 pH/N.A.	N.A./22 °C	N.A./37 °C	N.A./22 °C	N.A./37 °C	6,5 pH / 37 °C	7.2 pH / 37 °C
Extraction duration	2 h	1 h	1 h	24 h	2 h	24 h	1h+2h+3h	10 seconds	Up to 8 hours (2 hour intervals)

ANNEX XV INVESTIGATION REPORT – LEAD IN CONSUMER ARTICLES

* The method was further considered with personal consultation with an expert from Joint Research Centre

6.2.2.1. Migration testing within the framework of toys

Similar discussions on the suitability of testing methods, specifically focusing on the composition of the saliva used to simulate mouthing, took place within the framework of the regulatory measure for Toys (focusing amongst others, on phthalates (DINP)).

The Scientific Committee on Health and Environmental Risks adopted opinions in 2010 discussing different chemical migration and migration testing related topics (SCHER 2010a, SCHER 2010b and SCHER 2010c). In these respective opinions SCHER discussed the composition of the extraction medium, inclusion of chelating compounds as well concerns on the sample preparation and the influence it may have on test results.

On the composition of the extraction medium, SCHER disagreed in their evaluation of the migration limits for chemical elements in toys with the view of the RIVM that water could be used as an extraction medium. SCHER recommended the use of physiologically-based extraction tests for mouthing, i.e., artificial saliva (SCHER 2010a).

Within the framework on chemicals in toys, RIVM discussed the differences between saliva and water as an extraction fluid for chemicals simulating mouthing on toy matrices (Van Engelen 2008). According to Van Engelen et al. (2008) the European Committee for Standardisation (CEN) came to a conclusion in a technical report (CEN TC 252/WG 9/TG 2) that the composition of the saliva is not very aggressive or different from water and the outcome is usually within the same order of magnitude – therefore water was seen the most proper simulant for saliva. Other RIVM report (Oomen et al. 2004) discussed the need to have gained slight differences in migration rate when water and saliva were compared as extraction fluids (Van Engelen et al. 2008). Nevertheless, the report concluded that water as an extraction medium in practice is easy to use and leads to test that are reproducible to work with and resulting only in minor differences in comparison to with saliva simulant.

SCHER (2010b) also reviewed the Danish EPA survey and health assessment of chemical substances in jewellery⁵¹ and took precautions to compare lead migration results obtained with simulated sweat because of the differences in pH and chemical composition between these mediums. One example was the lack of chelating compounds that are present in the mouth and facilitate the dissolution of lead - such as lactic acid (SCHER 2010b).

In their opinion on risk from organic substances in toys, SCHER (2010c) recommended a saliva solution free from any chelating compounds, the composition of which is described in detail in a Joint Research Centre report (EUR 19826 EN⁵²). In this report a description is given of a standard operating procedure for the determination and release of Di-isononylphthalate (DINP) in saliva simulant from toys and childcare articles using a head over heels (HOH) dynamic agitation device (Simoneau & Rijk 2001). The recommendation by SCHER (2010c) was also to take into account the mechanical force applying HOH –method developed (EUR 19826 EN).

EUR 19826 EN by Simoneau & Rijk 2001 was based on the development work carried out by the so called Consensus Group, chaired by RIVM, which appointed TNO Nutrition and Food Research Institute to develop a routine laboratory method to determine the release of DINP

⁵¹ The basis of the exposure assessment for the restriction.

⁵² <https://ec.europa.eu/jrc/sites/jrcsh/files/Simoneau%20EUR%2019826%20EN%20toys%20DINP.pdf>

in toys (Rijk & Elert 2000).

The development consisted of comparison of *in vivo* –human studies against *in vitro* -methods that best reproduced the human study results for migration testing. During this work a saliva solution was developed based on literature research, consultancy from an oral biochemistry expert and previous examples of simulated saliva. Rijk & Elert (2000) concluded that deviations from human saliva are valid within the specific needs of testing.

In the case of phthalate esters solubility was of essence so Rijk & Elert (2000) reasoned that qualitative salt composition was not as relevant as the pH, and that the presence of proteins may have great influence on the test results. In the testing phase, a simulant saliva version containing mucus was experimented with but excluded from the recommended saliva solution as it seemed to work as a lubricant in the presence of agitation, thus reducing the migration of DINP (TNO report V2530/Rijk & Elert 2000). However, contrary to advice from the consulted expert, no other organic content was experimented with during the validation process. The use of amylase or albumin was suggested by an expert and a preliminary experiment discusses their use in the conducted and reported experiment, but the results are not reported⁵³.

The SCHER assessment on the migration analysis done by Danish EPA contained some additional concerns on sample preparation and on the so called “first-flush” effect as a possibility for some contaminants to leach more rapidly in the beginning (SCHER 2010b). The phenomena was argued to have basis on corrosion kinetics of metals and alloys; the metal release rate is initially faster in biological fluids or water and then decreases due to more corrosion resistant surface formatting over time (SCHER 2010b)⁵⁴. On sample preparation, cutting the samples to analysable size pieces requires the use of wax or some other coating material applied to freshly cut surfaces to prevent lead migration from the inner parts of an item. Combined with higher testing temperatures the wax may soften and compromise the cover, causing excess migration not representative to mouthing of the surface of the item only (SCHER 2010b).

In 2018, ECHA published an investigation report on scientific information in terms of available analytical methodologies to determine migration of lead from the different materials used in jewellery⁵⁵. One of the assumptions made on the basis of the report was that due to the complex shapes many jewellery may have, the resulting uncertainties of measurement may be significant⁵⁶. It is plausible that the same challenge may concern some of the consumer articles as well.

ECHA has observed that one of the most used method for lead migration testing for consumer

⁵³ Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on validation of test methods for phthalate migration expressed at the 17th CSTEE plenary meeting also made a note of this.

⁵⁴ SCHER (2010b) thus recommended performing repeated discontinuous extractions separated by a “dry spell” of the metal in order to mimic the mouthing behaviour of children, which is a dynamic process.

⁵⁵ The full scope of the report:

https://echa.europa.eu/documents/10162/13641/lead_in_jewellery_report_jan2018_final_en.pdf/f1342976-eb02-a8b5-465f-f2252ac21cbc

⁵⁶ DIN EN 1811 measures nickel release on articles (as a possible proxy for lead). This method for nickel was reported to have an uncertainty of 46 %, compared to 10 %.

articles is EN 16711-3⁵⁷ the determination of metal content for textiles. EN 16711-3 is a European standard for textiles, approved by CEN on 15 March 2019. According to CEN the standard is applicable for testing all possible materials within the scope of the restriction. It follows EN 1811 standard's procedure for the determination of nickel release from materials with direct and prolonged skin contact which has the limit value defined as the unit $\mu\text{g}/\text{cm}^2/\text{week}$.

As it is estimated that lead has a linear release from the tested materials, the test period for EN 16711-3 is set for one hour, according to the entry 63 of REACH article XVII limit value of $0,05 \mu\text{g}/\text{cm}^2/\text{h}$. Artificial saliva is used as a test medium according to the need to test lead release from mouthing of an item. The saliva applied in EN 16711-3 is also applied in another standard, DIN 53160, which estimates the colourfastness of articles for common use with artificial saliva. This artificial saliva solution seems to be the same that was developed for DINP-migration determination (EUR 19826 EN by Simoneau & Rijk 2001). It does not contain any enzymes or organic compounds but is rather a mix of different salts and has pH that is within physiologically relevant range for saliva. The testing temperature is also set to physiologically relevant limits. Mechanical agitation by shaker set for 60 strokes per minute is included in the testing process. The article is cut to homogenous test specimens, however cutting should be minimized and any exposed inner surface should be coated with wax or covering lacquer to prevent excessive migration from inner parts of the article.

Conclusion

In the absence of an existing standard to support the implementation of the restriction for lead in consumer articles, RAC recommended to develop a new standard on the basis of elements of existing standards, most notably DIN 54233-4 and EN 71-3. Throughout this development, a specific issue of concerns has been the composition of the extraction liquid. Similar developments had already taken place under the Toys directive. EN 16711-3 is a newly adopted European standard for the determination of lead release by artificial saliva solution, developed originally for textiles but applicable to all materials relevant in relation to Entry 63. Artificial saliva solution utilized in EN 16711-3 is not optimized for lead migration testing. Given the recent recommendation of the US EPA (2017) and those of SCHER (2010), the composition of the saliva may require re-consideration with view to achieving a method that is as accurate as possible. ECHA identified two methods applying physiologically based artificial saliva that have been used for testing similar articles and materials that are relevant for Entry 63 and could provide further insight in potential saliva solution development; the UBM-method (ISO 17924:2018) and the protocol by Urrestarazu et al. (2014).

6.2.3. Method accuracy

In accordance to the Commission's request to provide an assessment of the suitability of the testing methods in relation to Entry 63, a conceptual level approach of an accuracy evaluation was taken with sufficient scope to discuss the identified key aspects of the methods⁵⁸.

Accuracy of an analytical measurement can be defined by its precision and trueness (Table 10). Precision consists of repeatability and reproducibility; the ability to gain similar results

⁵⁷ EN 16711-3:2019. Textiles – Determination of metal content- Part 3: Determination of lead release by artificial saliva solution

⁵⁸ Evaluation of accuracy is a part of an analytical method validation which in practice is a complex expert field see e.g. <https://www.sciencedirect.com/science/article/pii/S0165993607000118>

carried out under the same conditions of measurement and changed conditions of measurement e.g. within and between testing entities, respectively. Trueness is the closeness of gained averaged values to the true value of a measurement and, which is often represented by an accepted reference value. Therefore, both high precision and high trueness are needed for high accuracy.

Table 10. Definitions of accuracy, precision and trueness of measurements after Menditto et al. 2007

Parameter	Definition
Accuracy of measurement	Closeness of agreement between a quantity value obtained by measurement and the true value of the measurement (BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML 1993)
Precision	The closeness of agreement between independent test results obtained under stipulated conditions (ISO 1993, ISO 5725-1 1998)
Trueness	The closeness of agreement between the average value obtained from a large series of test results and an accepted reference value (ISO 1993, ISO 5725-1 1998)

For an accurate method a validation process, monitoring and quantifying the repeatability and reproducibility of the test would give valuable information on its level of precision. The lack of reference distribution of values obtained from testing certified reference materials or for example data acquired *in vivo* may have an effect on the level of the trueness of the test via possible systematic error. Precision is more related with the possibility of random errors (Figure 5).

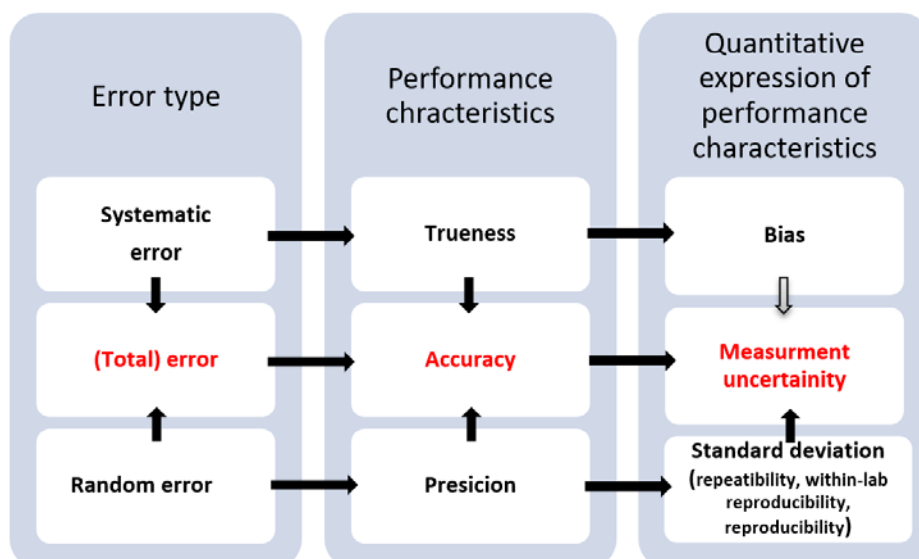


Figure 5. Relations between the error types, qualitative performance characteristics and their quantitative expression adapted from Menditto et al. 2007

A possible source of a systematic error may lie in the use of *a priori* assumption that a chosen method is able to capture values from the distribution of true values when the distribution is

not known. Therefore, it's theoretically possible to obtain values from a wrong distribution in a systematic way i.e. creating a bias (Figure 5).

In relation to lead migration testing it may be then problematic to choose an artificial saliva simulatant that is not optimized for the contaminant for which migration it should realistically represent. The method may then gain high precision through validation process, but it may not be accurate. Furthermore, the misestimating of agitation may under- or overestimate the exposure in some situations. On the other hand, the "first-flush" effect may yield higher estimates of the exposure if the level of migration would plateau after initial high result. Some articles have complex or otherwise difficult shapes to determine surface-wise. It may be that this is a possible source of random error, decreasing the precision of a method.

For the testing of corrosion and wear a meaningful assessment of precision and trueness is rather conceptual as any test will represent a practical application of simulating a wide range of possible articles and various ways to handle them. It could be argued that as the true representation of the wear and corrosion is likely to be unreachable, the precision of the method plays a more important role in terms of suitability of the method. Therefore, the ability to produce repeatable and reproducible results in terms of wear and corrosion adds more to the methods accuracy.

Finally, as the true value is a theoretical concept⁵⁹ and the situation where high precision is reached with seemingly low accuracy, the results may well be within statistical acceptability limits and represent the "true" value (Figure 6). In practice, this scenario would still require the appropriate estimation of the true value. If no *in vivo* or *in vitro* models are available to validate the results against, it seems justified that the test should then aim to simulate the actual circumstances of interest as accurately as possible.

⁵⁹ For example in the case of saliva composition, reaching the "true" saliva is not feasible as saliva is a complex biological fluid which contents vary temporally within as well as between individuals and sexes (Rijk & Ehlert 2000)

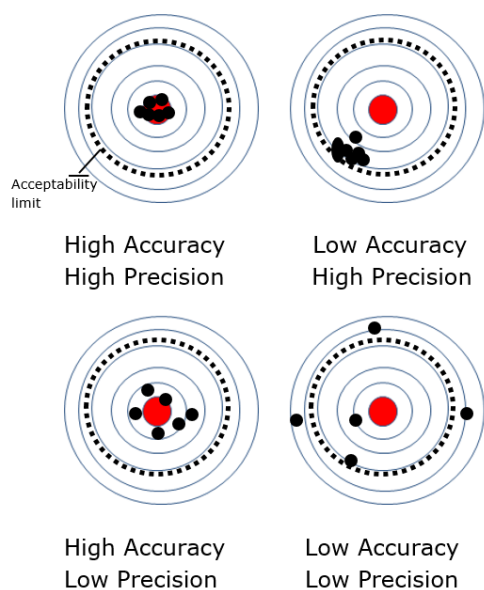


Figure 6. The relations between accuracy and precision of measurement results illustrated with black dots. Red area illustrates the true value and dotted circle the statistical acceptability limit for the result (Adapted from Feinberg 2007 and Royal Society of Chemistry 2003)

6.3. Overview of the feedback provided in consultations

ECHA has gathered information of the availability and suitability of relevant analytical methods through a call for evidence⁶⁰ and a targeted questionnaire to Forum members. In some cases, further information or clarification was enquired via email.

Altogether six members of the Forum responded to the survey. The specific set of questions shared with the members of the Forum in relation to the testing methods can be found in 8.2 (Annex 2). The call for evidence contained two questions relevant for the analytical methods and the responses to these question are reported and discussed within 6.3.2.

6.3.1. Feedback provided by the Forum

A questionnaire was shared with the Forum members inquiring their experience or the experience in their Member State on testing lead content and migration on coated and non-coated consumer articles. In total 6 answers were received by Member States and their enforcing authorities. Some additional, relevant, information was received outside the survey from one Member State's enforcing authorities and is reflected also in this section.

In addition to the general experience on testing the migration of lead from articles, and testing of the coating integrity of articles containing lead, the familiarity of some specific methods were asked as well⁶¹. Some of the respondents stated having no experience of any analytical

⁶⁰ <https://echa.europa.eu/calls-for-comments-and-evidence/-/substance-rev/23601/term>

⁶¹ EN 16711-3 and EN 12472

methods in relation to the question. Two respondents reflected with their experiences from nickel migration testing with EN 1811 as it was evaluated to some extent represent the testing of the lead migration. The concern of the uncertainty and potential variation raising from testing complex shapes was emphasized and questioning the quality of the results due to this reason was also included. One respondent pointed out their view that the limit of 0.05 µg/cm²/h is not a problem, however determining the surface is difficult due to diverse shape of the tested articles: “a good determination / calculation of the surface is almost impossible”. The respondent recommended to look at the total levels of lead content rather than migration. In the responses the suggestion was made that because the enforcement investigations often choose to look at simple forms when testing jewellery, the same may apply to lead migration in other types of articles.

Some respondents reported that the migration testing was left as a responsibility of the inspected companies and monitoring by the authorities is done only on the basis of the content. In one reply, a specific description of the process of testing the content with XRF-measurement was provided and it had been reported that if the material is or seems to be heterogeneous, several measurements from different parts of the item will be done. For coated articles, both the coating and surface underneath the coating are tested. After wet combustion the acquired liquid is tested for elements with ICP-OES.

Two respondents reported that in such situations where the limit of lead content has found exceeded in the testing, there has not been complaints on the basis of compliant migration results which would override the breach of content limit. The lack of prescribed analytical methods for entry 63 of REACH Annex XVII regarding lead migration methods was mentioned by one respondent and therefore only in few individual cases analysis was said to have been conducted according to the EN 1811 standard (albeit on jewellery only). In one case, the use of USEPA 3050B/3051/3051A and 3052 followed by ICP-OES (total lead in metals) was reported.

In relation to the wear and corrosion testing, some of the respondents didn't seem to have any practical experience on the specified method (EN 12472:2005+A1:20091) or any other, whereas some indicated experience due to the nickel testing and stated that the method would be useful also in lead migration testing. For some, the test was not seen having any immediate problems, however the description of the method was indicated to leave room for interpretation and thus having possible effect on the analysis of the results. The concern that consumer articles are used longer than the assumed and simulated two years was raised in one response, stating that it is not acceptable limit if lead is still released after that and furthermore, that the article is still harmful to the environment.

Other topics shared highlighted the possible fluctuations in results of these test methods and the need for standardized method that is tested for reproducibility in “round-robin” tests, producing data for validation of the results, and that relevant results should be verified by a second independent method to avoid false positives. Also the need for available and certified reference materials was raised. Finally, some critiques for the high cost and time requirements of migration as well as wear and corrosion tests were given.

6.3.2. The feedback submitted to the call for evidence

Two questions in relation to the testing methods were provided in the call for evidence. As the responses to these two questions overlapped substantially they are discussed and analysed together. The questions provided in the call for evidence related to the testing

methods were as follows:

1. What is your experience with analytical methods for determining that the rate of lead release from articles (coated or uncoated) does not exceed the limit of 0.05 micrograms/cm² per hour?
2. How would you describe the availability and suitability of these analytical methods?

In total 31 replies in relation to these questions were received (Annex 3).

Some respondents stated they had not the technical or economical means to conduct tests in-house. Indeed, especially when it comes to the methods for migration testing it is likely that these tests are conducted by professional laboratories rather than in-house. Also, the lack of knowledge or experience of suitable methods was reported by some respondents (5/31 and 15/31, respectively).

The European Copper Institute (ECI) emphasized in their reply that as they represent the producing and fabricating industry rather than the downstream industry, they have no experience in testing of final products using copper alloys with coated or otherwise treated surfaces nor with EN 12472. However, as reported by the ECI, in 2013 they submitted testing results from testing of bulk materials to ECHA in the course of the public consultation during the drafting of the restriction proposal in 2013. The results and applied protocol was published in 2014 and referred earlier in this report (Table 9) as the protocol by Urrestarazu et al. (2014). In the developed method an artificial saliva solution containing mucus was applied, and different lead containing brasses but also other alloys such as lead containing nickel silver were tested. The results indicated, that the lead migration rate in saliva might exceed 0,05 µg Pb/cm²/h when the content of lead in the alloy is above 0.5 %. RAC recommended a derogation for brass alloys in articles up to 0.5 % of content due to the results reported by the ECI. Some of the other replies referred to the aforementioned studies of metal migration into artificial saliva done by the ECI (Wieland Werke AG, ARGE and ELF), anticipating that, in line with the results of previously conducted studies, their or their stakeholders' manufactured lead containing brass and lead containing nickel silver products with a range of 1-3.5 % of lead content would not comply with the migration limit. It seemed this had not been confirmed by testing of their own products by the manufacturers themselves.

A number of respondents, however, had experience on different testing methods for the migration testing, such as EN 16711-3. One representative from the musical instrument industry (name confidential) stated that their company tested silver plated as well as non-plated brass mouthpieces having total lead content of about 3 % with EN 16711-3 and the limit of 0.05 µg/cm²/h was not exceeded. The company provided ECHA with the testing results via the laboratory conducting the tests (see confidential annex). Three other stakeholders from the musical instruments industry referred to these reports (Bundesverband der deutschen Musikinstrumentenherstellere. V.NGO, IfM-Institut für Musikinstrumentenbaue.V.NGO and MASTER MUSIC SRL).

Buffet Crampon Germany GmbH reported to have tested for wear and corrosion as well as migration, but that there has been significant variation between and within patches and testing houses. The lack of predefined standard test piece for wear and corrosion test was seen as an affective factor, having influence on the amount of the testing fluid also. One stakeholder (name confidential) noted that there are efforts lead by a volunteer group of German analysis laboratories to see if the analysis approach of EN 16711-3 leads to reproducible results. This group is planning to perform a circle analysis to compare the results

of a set of products⁶².

One company (ALBORCH Y VIDAL S.L) reported to have tested their curtain weights with EN 71-3 and the resulting migration values did not comply with the required limit. The company stated to have seen this as an opportunity and substituted via R&D to other material which is lead free. In relation to batteries, Handelsverband Deutschland (HDE) reported that the availability of the test method is considered sufficient to good, however the cost was evaluated about twice as high as that of a lead compound content test and requiring more time. They had not experienced any differences in results when testing between coated or non-coated items⁶³.

Two replies referred to EN 12472 standard stating that the test does not represent or reproduce the practical application or handling of the article or material⁶⁴. One company (name confidential) reflected that as EN 12472 has been developed for articles containing nickel and that the applications of nickel and lead are very different to each other and that lead containing items are not as often – or at all – in contact with the body or skin.

The Japanese electric and electronic (E&E) industrial associations (JEITA, CIAJ, JBMIA and JEMA) replied in relation to lead in batteries that they believe that the method stated in IEC 63000 or IEC 692474 is more appropriate to manage substances in articles in global supply chains as inclusion test of substances in an article is not mandatory in managing substances in articles under EN IEC 63000 which is harmonized with the RoHS Directive. They added, referring to migration testing, that migration test of substances is not mandatory.

The Professional Association of French Enamellers responded with a concern that craftsman companies are not able to carry out repetitive tests due to their costs. One company experienced in testing (Handelsverband Deutschland (HDE)) reported the test cost of migration being almost twice in comparison to content test.

6.3.3. Feedback from other expert consultations

In addition to the call for evidence and survey for the Forum, ECHA contacted three specialists in the field of chemical testing and coatings for expert consultations to discuss issues raised during the Agency's investigation.

CEN and TÜV Rheinland representatives provided insight on the EN 16711-3 and how it compares to other testing methods such as the protocol by Urrestarazu et al. 2015, especially in relation to accuracy. The suitability of corrosion and wear testing, EN 12472 was also discussed. Aforementioned issues were also discussed with the technical director of the Assay Office. All three experts contributed to the conclusions and recommendations.

To assess the relationship of lead migration and content tested with EN 16711-3, ECHA assessed a data set (n=241) of various consumer articles, applying different materials, tested with 16711-3.

⁶² ECHA was not provided with any further information of the group

⁶³ The test's in question were not specified

⁶⁴ The articles in question were keys (851) and clocks (847).

6.3.4. Conclusions from the feedback

Many of the enforcement authorities have left the testing of lead migration for the market actors. This can be reasoned by the wording of entry 63 of REACH article XVII paragraph 7⁶⁵ which states that the content limit shall not apply if it can be demonstrated that the rate of lead release from an article does not exceed 0.05 µg/cm²/h. Enforcement authorities rather opted to test the content of lead. There was no experience of market actors providing migration testing results to demonstrate compliance on the basis of migration clause in situations where the content limit was exceeded.

Due to the lack of experience, many respondents of the Forum survey reflected only on their experiences from testing of the nickel release with EN 1811. From the responses it appears that the main concern is the complexity of the tested items that was also seen to cause desire to test simpler forms. The desire for standardized method that is tested for reproducibility and validated in “round-robin” tests and that relevant results should be verified by a second independent method to avoid false positives was expressed. Also the need for available and certified reference materials was raised.

On the basis of the responses from the call for evidence, the possible testing methods for lead migration were not familiar to all manufacturers and many saw them as impossible to conduct in-house and/or too expensive to outsource. Overall, most of the replies received came from manufacturers of derogated articles who are not under the obligation to test the migration to comply with the current legislation. However, one company reported to have substituted through innovation their non-derogated consumer article’s material to lead free alternative.

The replies from ECI, ARGE and some of the article manufacturers reflected the situation with testing of lead containing brass alloys which are derogated up to 0.5 % of content⁶⁶ on the basis of the estimated lower migration of lead from these articles. ECHA received testing reports indicating article compliance with the migration limit for coated and non-coated articles with ~ 3 % of lead content tested with EN 16711-3, whereas some respondents referred to ECI’s tests (see Urrestarazu et al. 2014) on bulk brass materials with similar lead content, anticipating that their articles will not comply. However, no actual testing of the articles was reported in these cases. A battery manufacturer reported good results (test method not further specified), with no differences between the coated or non-coated items. A group of independent laboratories testing the EN 16711-3 for its accuracy was reported, however no further info of this was provided to ECHA despite additional inquiries.

Information received via the expert consultations in relation to migration methods included further concerns of the level of agitation having effect on lead release from the article and this aspect being especially relevant for metallic articles⁶⁷. In addition, the specific lack of lead migration from brass articles containing up to 3 % of lead when tested with EN 16711-3 in comparison to results obtained by Urrestarazu et al. (2014) was evaluated to possibly originate due to a number of factors; differences in the surface of the item tested which affects the corrosion potential, differences between the artificial saliva or the difference between the tested items i.e. bulk material or article. Also, one reason could be the profound metallurgical

⁶⁵ <https://echa.europa.eu/documents/10162/3f17befa-d554-4825-b9d5-abe853c2fda2>

⁶⁶ Paragraph 8(g) : <https://echa.europa.eu/documents/10162/3f17befa-d554-4825-b9d5-abe853c2fda2>

⁶⁷ Personal communication with Mr Dippal Manchanda, technical director Assay Office

differences in the brass matrix that account for the migration in ways that cannot be anticipated without testing. This may imply that content is not appropriate indicator for migration level⁶⁸. However, EN 16711-3 was also highlighted for being a stable and therefore repeatable method with manageable complexity and providing reproducible results⁶⁹.

During the expert consultations it was concluded that aforementioned aspects could be looked into further for the benefit of method accuracy. A benchmark study involving different artificial saliva solution's as well as different levels of agitation would reveal if the deviations between the results potentially raising from these different aspects exceed statistical acceptability limits.

To further clarify the possible issues of EN 16711-3 and feasibility of benchmark testing, ECHA requested migration data from various consumer articles tested by TÜV Rheinland. Overall, the analysis of the migration data received did not show any linearity between the content and the migration of lead in the tested articles. Therefore, it cannot be concluded on the basis of this limited data set that the only differences in artificial saliva solution in EN 16711-3 would account for the discovered inconsistencies between anticipated and realised migration of lead in relation to content. However, this cannot be excluded either. Based on two expert opinions, linear relationship between lead content and migration has not been discovered in practice. Factors affecting the migration can include not only the applied saliva solution but also the characteristics of the article surface in terms of material and corrosion. The level of applied agitation should also be considered between different materials.

In relation to EN 12472, expert consultations verified satisfaction and also emphasized the need for wear and corrosion testing when testing of lead migration. However, attention should be given to the contents of abrasive paste if the composition is to be changed as the texture of the paste may facilitate polishing of the surface of the article. The shape of the surface may have an effect in lead migration; less polished surfaces may release more lead⁷⁰. The Forum survey indicated mainly experience from EN 12472 due to the nickel testing and stated that the method would be useful also in lead migration testing and no immediate problems were foreseen for this use. The exception was the concern of method description leaving room for interpretation and that consumer articles are used longer than the assumed two years. In the call for evidence, the concern that the test does not reproduce practical application or handling of the material or specific article was raised twice. Also, the lack of predefined test piece of an article was seen as a source of possible variation in the results. Finally, one respondent in its reply noted that many of the consumer articles are not in contact with skin unlike the items in the scope of the nickel directive.

6.4. Conclusions

6.4.1. Migration methods for lead release

The need to develop a reliable migration testing method for the purposes of entry 63 of REACH article XVII was acknowledged in the reasoning of the Background Document for SEAC and

⁶⁸ Personal communication with Mr Martin Baker (Agoss and CEN expert member) and Dr Ansgar Wennemer (TUV Rheinland)

⁶⁹ Ibid.

⁷⁰ Personal communication with Mr Dippal Manchanda, technical director Assay Office

RAC opinions (2014). Combining suitable elements from EN 71-3, a method utilizing fluid mimicking gastro-intestinal compartment to DIN 54233-4, a method employing artificial saliva, was suggested as a basis to the development of a new migration testing method simulating mouthing only. EN 71-3 as such was suggested as a transition period option despite of its potential to overestimation of exposure. The most discussed item seems to have been the content of the artificial saliva and therefore this investigation report initially approached the matter from that point of view. Additional aspects such as pH of the artificial saliva, temperature of testing conditions and the duration, as well as the possible need for agitation, determining and processing of the test piece and some other process related issues were also identified.

To provide an assessment of the testing methods suitability to determine that the rate of lead release from (coated or uncoated) articles does not exceed the limit of 0.05 µg/cm²/h, a conceptual level approach of an evaluation of accuracy was taken. Accuracy can be defined by the method's level of trueness and precision. Some possible general factors compromising trueness and precision were defined, such as if the test method is not able to capture the true value of the migration. Precision might be affected if the repeatability, the precision a test result can be repeated within a testing entity, and reproducibility, the precision a test result can be repeated between the testing entities, of the methods are not within accepted margins of error.

In 2019 a European standard EN 16711-3 for the determination of lead release by artificial saliva in relation to determination of metal content from textiles⁷¹ was approved. EN 16711-3 applies the saliva solution developed originally for EUR 19826 and currently also applied in DIN 53160-1: 2010-10 (determination of the colourfastness of articles for common use with artificial saliva). It was confirmed to ECHA that several, big testing entities apply regularly this European standard as standard operating procedure, indicating a clear improvement to the ability of the market to comply to entry 63 of REACH article XVII and with enforcement ability to monitor of it. As a CEN approved standard and already progressively adopted, EN 16711-3 is likely to harmonise the testing situation on the market and make results more comparable in comparison to situation where entirely different methods and/or standards are used.

In relation to any testing methods accuracy, its ability to measure the true value is a factor of interest as inability can create biased test results. Possible source of a systematic error may rise from the *a priori* assumption that a chosen method is able to capture values from the distribution of true values when the distribution is actually not known. In relation to the desire for method validation raised in the consultations, it was confirmed by CEN that the artificial saliva applied in EN 16711-3 has not been validated against *in vivo/vitro* results and it may be possible that it decreases the ability of the test to acquire true values. The contents of surrogate fluids for migration testing may have an effect to the gained result; the presence of e.g. chelating compounds may be important especially in metal migration testing and adding of organic compounds, enzymes and mucus has been suggested for more physiologically based testing (EPA 2017, SCHER 2010).

ECHA and the consulted CEN experts agree that EN 16711-3 level of accuracy could be

⁷¹ Standard is however applicable to all materials relevant for entry 63 of REACH article XVII

increased by method validation. According to ECHA's investigation this type of robust method development and validation of methodologies has been undertaken for the release of diisononylphthalate (DINP) in saliva simulant from toys (EUR 19826 EN) by the JRC. The artificial saliva developed for the purpose is a mix of salts as adding of mucus to the mix in the development phase was discovered to work as a lubricant in the presence of aggressive head-over-heels agitation. The method was developed against *in vivo*-results.

Despite the proportion of responses indicating no knowledge or experience of testing lead migration⁷², some feedback also from the Forum survey and call for evidence indicated the desire for a lead migration method validation and verification and testing against other methods, to some extent due to the fluctuations and complexities in defining the surface area of the tested article.

ECHA acknowledges that the development, testing and validation of any method consists of complexities beyond what discussed in this report and that some of the possible shortcomings in precision and trueness of the test may well be within acceptable statistical limits. Furthermore, such testing would require substantial amount of time. However, as lead is a non-threshold substance with especially detrimental effects in the neurodevelopment of children, an overall high level of accuracy is desirable.

A benchmarking exercise between different saliva solutions would be sufficient to demonstrate if the magnitude of the differences and variation between different artificial saliva's are statistically significant and therefore constitute a cause of concern due to decreased trueness. Should such benchmarking exercise take place, differences between the set levels of agitation and tested materials (e.g. metal and textile) should also be investigated as per recommendation from the expert consultation discussed in 7.3.4.

A further motivation for the aforementioned benchmarking exercise can be seen from responses from the call for evidence, where it was reported that some of the brass articles were found compliant with EN 16711-3 for lead migration despite a lead content of 3 %. This may raise some concern on the accuracy of the used method EN 16711-3. Entry 63 of REACH article XVII derogates brass alloys up to 0.5 % of content on the basis of lower lead migration. The studies this derogation is based on reported values of migration approximately 0.240 µg/cm²/h for the content of 3.1-3.5 % whereas according to the testing reports provided for ECHA migration at content limit of 3 % was not detectable (Urrestarazu et al. 2014). It needs to be noted that the studies were done for bulk material, not articles. Nevertheless, the study was also offered as a reasoning for some of the derogated articles inability to comply with Entry 63 during this investigation. The differences between these tests may rise from the use of different artificial saliva solution.

6.4.2. Corrosion and wear test methods

Before the similar need for testing lead containing items, the wear test method EN 12472 was to be used prior to the testing of nickel release⁷³ from coated articles that come into direct and prolonged contact with the skin during a period of two years of normal conditions of use.

⁷² EN 16711-3 was adopted in 2019 and therefore the experiences from this specific standard are not assumed to be numerous.

⁷³ EN 1811, Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin

The method applies a practical approach combining both wear and corrosion in the same test. Some of the articles in scope of the restriction are not meant for wear or are unlikely to be in prolonged contact with the skin unlike with the articles in scope of the nickel directive. Therefore it might be argued that the trueness in such cases may be compromised. However, it seems likely that the aforementioned situation is over- rather than underestimation of the effect on the durability of the coating. As for the other chosen aspect to estimate the possible accuracy of the method, precision, it may be that defining the piece to be tested from the article may be a source of variability when a standard test piece is not defined.

ECHA consulted experts in the field of surface chemistry and corrosion in relation to the EN 12474 and its suitability for testing lead containing consumer articles. The consulted experts were of the opinion that the test is well suited for this use and there is much experience from it due to the previous use in relation to nickel release testing. Variations on the level of corrosion may however rise if the contents of the abrasive paste are changed as it may facilitate polishing of the surface of the item. The shape of the surface may have an effect in lead migration; less polished surfaces may release more lead. The lack of proximity with skin or the simulated duration, concerns raised in the call for evidence and survey with the Forum, were seen secondary in comparison to providing efficient corrosive simulation leading to changes in the article surface that will promote possible lead release. Essentially EN 12472 was seen fit for this purpose.

6.5. Recommendations

6.5.1. Migration test method EN 16711-3

After having consulted with the previously identified experts⁷⁴, the conclusion of this report vis-à-vis the suitability of the migration test method EN 16711-3 is:

- The current practice of applying method EN 16711-3 appears to be suitable; the method is stable and the results from the test between laboratories are comparable. This is very important for market actors as it provides a stable scheme of testing with precise results. It is also important for enforcers as tests can be compared with each other.
- Following the discussions in SCHER that were held within the framework of the Toys directive and recent considerations by the US EPA, the added value of a different composition of the extraction liquid (artificial saliva) in EN 16711-3 could be examined further, investigating the possible differences when applying different physiologically based artificial saliva solutions containing e.g. relevant acids and mucus.⁷⁵
- As the level of agitation during the testing has an effect for the contaminant release, relevant and protective level of agitation within the context of mouthing should be considered and tested. Furthermore, attention should be given for the possible differences arising from testing of different materials.

⁷⁴ See footnote 65 and 66.

⁷⁵ The artificial saliva's applied in the UBM-method and in the protocol by Urrestarazu et al.(2014) could provide alternatives for such investigation (see table 9).

The added value of obtaining more accurate test results with the change proposed under the second bullet point above would need to be balanced against:

- The cost and time needed to develop a more advanced methods, in discussion with consulted experts⁷⁶ it was brought forward that the development of a completely new test method could take up to six years.
- The increased complexity and possible instability of testing such a change would bring along vs its current simplicity and precision.
- Cost for performing tests, the current test are already significant compared to lead content testing⁷⁷.

Of the possible consequences mentioned above, especially the increased complexity of the test method and the possible increase in variability between the results of test laboratories requires particular attention vis-à-vis the objective of the regulation; to provide a protective measure for children against exposure to lead.

In theory, an optimisation of the extraction liquid could make the testing more accurate, but care needs to be taken that this does not increase the variability of testing (between tests and between test laboratories) as this could increase the frequency of *false positives*.

We therefore recommend that, as a starting point, a benchmark exercise of different saliva solutions with reference materials and actual articles could be undertaken. The purpose of such benchmarking is to understand whether such testing would indeed give more accurate testing results. This should be weighed against the additional benefits the current testing methods may have by being protective enough.

RAC based the migration limit set for brass containing items on the results obtained by Urrestarazu et al (2014). No actual testing of articles had been undertaken within the context of that study. From the information that had been submitted in the call for evidence, it was brought forward that actual testing has not been undertaken by the European Copper institute (ECI), so far the need for this was not identified as the ECI does not represent directly any downstream users.

Although not part of the original request, during the investigation ECHAs found that lead content in brass may not be directly related to lead migration from brass.

Based on various inputs (stakeholder discussion and input to the call for evidence) it is expected and seen in reality that migration limits in actual brass containing articles can be below the migration limit when tested with EN 16711-3; information had been provided to ECHA that demonstrated that for example no detectable level of migration was seen in brass with contents of around 3 % of lead.

Therefore, a difference between the testing of the material only and the testing of actual articles occurs. The difference between these results could be due to

1. The fact that article surfaces are often treated (polished) and it reduces the corrosion potential in actual articles. However some level of polishing was done in the protocol

⁷⁶ See footnote 65 and 66

⁷⁷ Cost of pricing discussed with TUV Rheinland, exact prices claimed confidential.

by Urrestarazu et al. (2014) also. The study also applied mucus in the saliva solution which EN 16711-3 saliva solution does not contain, implying that the content of the saliva may also have an influence on the testing results.

2. The profound differences in the brass matrix that account for the migration in ways that cannot be anticipated without testing. This implies that content is not an appropriate indicator for migration level.

6.5.2. Wear test method EN 12472

From a practical point of view most stakeholders were satisfied with the method EN 12472 and thought that it could be applied to lead as well. The method is considered to be a practical solution for wear (and corrosion), the only critique that was brought forward was that the definition of the sample size has not been predefined. This could potentially lead to variations in test results between laboratories.

The aspect of trueness is less valid for EN 12472 as it is a practical test and the precision aspect is more relevant (no true level of wear and corrosion can be defined for the wide variety of consumer articles that in practice will be tested).

All consulted experts considered the method to be reliable and suitable and no actions are required in terms of improving the current test method EN 12472.

7. Conclusions & Recommendations

7.1. Derogations

Keys and locks, including padlocks

The three potential alternatives for substituting lead in brasses are silicon (Si), bismuth (Bi), and sulphur (S), however, they are not considered suitable for substituting lead in keys and locks, including padlocks. According to confidential tests, Si-brass, the most technically advanced alternative, does not meet the technical material requirement of keys, locks and padlocks due to decreased sliding behaviour and inferior surface quality of the final parts. While Bi-brasses are not considered a viable alternative by the industry due to toxicity of Bi and its salts and disruption of the copper recycling loops (due to cracking of alloys containing Bi during hot use). Brasses where lead has been replaced by sulphur have been used for water drinking application, for applications outside of that scope sulphur (to replace lead in brass) has not been explored yet. On the other hand, no feasible lead-free alternative for lead-containing nickel silver has been discovered.

Based on the information gathered during the call for evidence and the contract with Eftec, it is evident that currently there is no technically and economically feasible alternative to lead in brasses and nickel silver in keys and locks, including padlocks.

In the call for evidence industry had not submitted information on migration test and their outcomes for this specific articles group.

In the absence of information on migration form this article group, ECHA is not in a position to conclude on whether migration limits were fulfilled for these articles. Industry is advised to collect migration data in order to demonstrate compliance with the migration limits in entry 63 should the derogation be removed.

Musical instruments

In woodwind and brass instruments lead is used in the bending parts which are on the bodies of brass instruments, in mouthpieces and in solders. For bending parts / bodies of brass instruments and mouthpieces, the main alternatives, are Si, Bi and sulphur. As with keys and locks, these alternative materials encounter the same issues with tightness, machinability, reliability of contacting, sliding / gliding, mechanical properties and corrosion resistance. On the other hand, there are lead-free alternatives to lead in *solders* available on the European market, and some companies have already switched to these alternatives. However, it was emphasised that the solder is used inside the instrument, hence it cannot be mouthed during normal and foreseeable use of the instrument.

Based on the information gathered during the call for evidence and the contract with Eftec, it is recommended that the derogation is maintained with regard to the bending parts / bodies of brass instruments, as currently there are no suitable alternatives or a clear evidence supporting that the lead migration is within the limits.

Tests for lead migration conducted in accordance with EN 16711 indicate that both coated and uncoated brass mouthpieces containing approximately 3 % lead are compliant with the lead migration limit. However, the information came from a single source and was limited to three

tested items only. We did not receive any evidence confirming that this is valid also for nickel-silver mouthpieces containing 3 %. Hence, it is recommended that before reconsidering the derogation for mouthpieces a further investigation is conducted with regards to the lead migration of both coated and uncoated brass and nickel silver mouthpieces,

Solders fall outside the scope of the restriction as they are used inside the musical instruments and hence they cannot be mouthed during normal or foreseeable use.

Religious articles

In addition to the lack of information on alternatives in the Annex XV restriction proposal, there was a lack of stakeholder engagement in the call for evidence thus no information was provided by any stakeholders. In the absence of new information on possible alternative materials to lead in religious articles and on the impact of restricting lead in those articles, ECHA is not in a position to advise the Commission whether to continue exempting religious articles or not.

Portable zinc-carbon batteries and button cell batteries

The zinc-carbon round cells and zinc-carbon volt-blocks have a lead content in the range of 178 – 1958 mg lead per kg and 535 – 1103 mg/kg, respectively, thus exceeding the limit of 0.05 % by weight of the article. Currently, it is estimated that they represent 10 % of the market and their share is “naturally” decreasing as a result of the transition from old devices with low technical requirements to modern articles requiring both higher battery capacities and higher peak currents. Technically and economically feasible alternatives already available on the market are alternative battery systems / chemistries, such as alkaline-manganese and nickel-metal hydride batteries or lithium-ion batteries. Even though the alkaline batteries’ price is as twice higher than the price for zinc-carbon batteries, the absolute price difference for consumers is low - in the range of €0.50 – €1.00 per battery.

In the light of the new information gathered during the call for evidence and the contract with Eftec, with regards to the lead content of zinc-carbon batteries, market dynamics and availability of alternatives, it is recommended that the derogation on zinc-carbon batteries is removed. In particular, zinc-carbon batteries have a lead content well exceeding the threshold of 0.05 %, the market share of zinc-carbon batteries is steadily decreasing due to consumers switching to modern devices and there are available and affordable alternatives on the market.

Based on the new information gathered during the call for evidence, the lead content in button cell batteries is within the limit of 0.05 %, it is therefore recommended that the derogation is removed.

7.2. Migration test methods

Based on the analysis provided in section 6.5.1. it is recommended to perform a benchmarking exercise which would entail taking a sample with known lead content and migration rate, then testing it with EN 16711-3 using different artificial saliva compositions, under different agitation conditions, and see whether either the saliva or the agitation or both influence the migration rate.

EN 16711-3 is a newly adopted European standard for the determination of lead release by

artificial saliva solution, developed originally for textiles but, according to the experts consulted, applicable to all materials relevant in relation to Entry 63. However, artificial saliva solution utilized in EN 16711-3 is not optimized for lead migration testing. Although there are improvements possible to the existing testing method EN 16711-3, the further improvements and possibly the development of a new standard from scratch is a resource consuming activity and should not be engaged in without a solid justification.

In line with discussion within the framework of the Toys directive, the actual composition of the extraction liquid (artificial saliva) could be optimised further. Any such improvements needs to be considered keeping in mind the purpose of the regulation the testing methods are required to support: offering an adequate level of protection of children against the harmful effects of lead in articles.

The possible improvements to the testing method EN 16711-3 could lead to a further optimisation of the extraction saliva that may give a better understanding of migration of lead from articles and increase the trueness of the method. This needs to be weighed against some possible other effects: increased complexity of testing and possible greater variation between tests.

7.3. Wear test methods

Based on the analysis provided in section 6.5.2, the method EN 12472 is thought to be practical and suitable also for lead. No changes to the method are recommended.

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⁷⁸ (Crystal glass is addressed under analysis of Exemption 29 on page 679 of the report).

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Annexes

Annex 1: Stakeholders participated in the call for evidence and stakeholders contacted by contractor and ECHA

Table 11: Stakeholders participated in the call for evidence and stakeholders contacted by contractor and ECHA

Stakeholders participated in the call for evidence	Stakeholders contacted by contractor and ECHA
ALBORCH Y VIDAL S.L	ARGE – The European Federation of Associations of Locks & Builders Hardware Manufacturers
ARGE – The European Federation of Associations of Locks & Builders Hardware Manufacturers	DIEHL Metall, Sundwiger Messingwerk GmbH & Co. KG
[REDACTED]	European Copper Institute (ECI)
[REDACTED]	[REDACTED]
Benedikt Blasinstrumente Eppelsheim	Petrof spol. sr.o.
[REDACTED]	[REDACTED]
Buffet Crampon Germany GmbH	The UK Music Industries Association
Bundesverband der deutschen Musikinstrumentenhersteller e. V.	Syndicat Professionnel des Emaillieurs Francais
Chambre syndicale de la facture instrumentale- CSFI	The British pewter association & Worship Company of Pewterers
Chelsea Clock	Handelsverband Deutschland (HDE)
DIEHL Metall, Sundwiger Messingwerk GmbH & Co. KG	KiK Textilien und Non-Food GmbH
ELF - European Locksmith Federation	Finnish Safety and Chemicals Agency (Tukes)
European Copper Institute (ECI)	Eurofins
[REDACTED]	Allgemeine Gold- und Silberscheideanstalt AG (Agosi)
Handelsverband Deutschland (HDE)	TÜV Rheinland Group
IfM-Institut für	Abloy Oy

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Musikinstrumentenbau e.V.	
Japan Electronics and Information Technology Industries Association (JEITA)	Chelsea Clock
Josef Klier	
██████████	German Environment Agency (UBA)
MASTER MUSIC SRL	Assay Office - Birmingham
██████████	Bioaccessibility Research Group of Europe (BARGE)
Member State - Germany	Finnish Customs
Metallblasinstrumente Bernhard Willenberg	
Petrof spol. sr.o.	
██████████	
Syndicat Professionnel des Emaillieurs Français	
Wieland Werke AG	
Wilhelm Heckel GmbH	
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████████████████████	
Zirnbauer GmbH	

Annex 2: Contacted Forum Members

FORUM members were contacted with a questionnaire inquiring their Member state experience on testing lead content and migration on consumer articles. In total 6 answers were received. The specific set of questions shared with the members of the Forum in relation to the migration testing were the following:

1. What is your experience with analytical methods for determining that the rate of lead release from consumer articles (coated or uncoated) does not exceed the limit of 0.05 micrograms/cm² per hour?
2. Which were/are the most critical aspects you had/have to deal with, when performing the tests? Which analytical methods were/are used?
3. What is your experience and/or expert opinion on the suitability of the EN 16711-3:20191 (Textiles – Determination of metal content – Part 3: Determination of lead release by artificial saliva solution) for determining that the rate of lead release from consumer articles (coated or uncoated) does not exceed the limit of 0.05 micrograms/cm² per hour?
4. How would you describe the suitability of the wear test method EN 12472:2005+A1:20091, as well as the availability of other methods, to determine the coating integrity of articles containing lead in order to ensure that the release rate of lead is not exceeded for a period of at least two years of normal and reasonably foreseeable conditions of use of the article?
5. Any other topic you think may be relevant for the assessment of the aforementioned testing methods and their ability to facilitate the enforcement (e.g. costs, relevancy, reliability, practicability and reproducibility).

Replies to question 1:

- *In Sweden enforcement has had no reason to test migration. We have left the responsibility to the inspected companies. We only test content of lead in the articles. None of the inspected companies have questioned our results and none of the companies have provided us with a migration test on the article. (Sweden, Kemi)*
- *The limit of 0.05 µg / cm² per hour is no problem. Determining the surface becomes very difficult. The products are so diverse in shape that a good determination / calculation of the surface is almost impossible. This is comparable to the nickel migration from jewelry. There you must cover everything that does not come into contact with the skin with a lacquer and then determine the contact surface. The different forms of jewelry ensures that enforcement investigations often choose to look at simple forms. This often involves studs of earrings and piercings or cover plates of watches. I see the same problem with lead. It is much better to look at a total level and to link a restriction to. (Netherlands)*
- *Due to the lack of prescribed analysis methods regarding lead migration according to entry 63 of REACH Annex XVII, analysis was so far only conducted in a few individual cases, f.e. jewellery containing particularly high amounts of lead. (Germany)*
- *We have undertaken market surveillance checks on consumer items, contracting analysis of lead release to accredited laboratories. We have previously assessed articles for lead content rather than lead migration rate. (Ireland/HAS)*

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- *No experience of lead release, but experience of nickel release. (Finland, TUKES)*
- *No specific experience. (Denmark)*

Replies to question 2:

- *No experience (Sweden, Kemi)*
- *USEPA 3050B/3051/3051A and 3052 followed by ICO-OES (total lead in metals)(Ireland)*
- *We have experience on nickel release and that's similar to lead release. In both wear test method and nickel release method the measurement uncertainty is very high. Both tests are expensive and time consuming. There is no pre-test for migration. (Finland)*
- *Tests for nickel migration showed that determining the surface area of jewellery and other complex objects is quite difficult, which can lead to significant variations. This can result in widely different for objects of similar size and form. Also, the analysis method DIN EN 1811 prescribes a minimum surface area of 0,2 cm². Experiences show that this value usually needs to be doubled to allow for an adequate amount of testing solution. Thus, a limit value of 4 µg/l and a detection limit of 0,8 µg/l is applied. The usual testing devices have difficulties handling this. Results of tests for migration rates are subject to greater fluctuations than tests for content by weight, thus there can be problems with the quality of these checks. Also, the release rate depends on various factors that can vary between samples. One of our enforcement authorities reported that they use the DIN EN 1811 and DIN EN 12472 for the analysis in these cases. They reduce the migration duration in accordance to the DIN EN 1811. (Germany)*

Replies to question 3:

- *One of our enforcement authorities reported using the method in the past. Based on their experience, the test sample should not be cut into smaller parts and the test should be conducted considering the surface area of the sample. Also, cutting edges should be sealed. The legal basis for the test assumes that 0,05 µg/cm² is equal to 0,05 µg/g/h. This assumption seems questionable, thus referring to the weight of the sample should be avoided. (Germany)*
- *No experience (Sweden)*
- *We have not previously used this method. (Ireland)*
- *No experiences are available. The NVWA doesn't uses the mentioned test. (Netherlands)*

Replies to question 4:

- *Our enforcement authorities could not report practical experiences with this method. Considering the similarities to testing for nickel migration of coated jewellery, they see no immediate problems with applying the method to lead migration. (Germany)*
- *No experience. (Sweden)*
- *We have not previously used this method. (Ireland)*
- *This doesn't tell anything about the situation when a child swallows an item. And what about after 2 years use? I think that this is not suitable test for lead. (Finland)*

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- *Past experiences using the method for checks on nickel migration indicate that the method would be useful for checks on lead migration. The corrosion method described in the EN 12472:2005+A1:2009 is suitable to test the integrity of coatings. Though the description of the method leaves some room for interpretation which can have an effect on the analysis results. (Germany)*
- *The NVWA is already using the aforementioned standard for nickel migration. (Netherlands)*

Replies to question 5:

- *I think that these items are used more than 2 years and it's not acceptable if lead is released after that. Also those items are harmful to environment. For market surveillance purposes those methods are too unreliable, slow, expensive and they don't tell the actual situation. Fineness restriction is more fair to everybody. (Finland)*
- *A standardized method, tested for reproducibility in round-robin tests, should be developed. Relevant results should be verified by a second independent method to avoid false positives. (Germany)*
- *Due to the aforementioned fluctuations, a harmonized and clearly described analysis method is required. This includes universally available and certified reference materials. Also, data for validation of results is required (f.e. on reproducibility and the recovery rate). This is especially necessary for the reliable detection of limit value violations. (Germany)*

Annex 3: Call for evidence – replies to questions in relation to testing methods

842/Syndicat Professionnel des Emaillleurs Français, Trade Union France/Enamels

- *Any.*
- *The Saint Paul glassworks (87 FRANCE) carries out analyzes and has data. Craft companies in the sector can not afford to carry out repetitive analyzes.*

845/Individual/Germany/Musical instruments

- *Unfortunately, I have no experience with such an analysis method. According to our own research, such an analysis involves a great deal of time, cost and technical effort, which also requires certain knowledge in the chemical field. For a small and medium-sized enterprise, this is simply not feasible.*
- *No availability available. Therefore, unfortunately, I cannot provide information on such a method.*

847/Chelsea Clock, Company/United States/Clocks

- *Only anecdotal evidence from customer testing. "Tumble testing" has been used on our products to simulate handling over a period of time. We feel this method does not accurately represent or reproduce the minimum handling of a typical clock.*
- *We do not have enough experience yet to comment on this. However, we submit that any testing must take into account that a clock is not handled or in contact with a consumer except for winding, battery changes, or time setting.*

848/Individual/Germany/Musical instruments

- *I am not aware of any such method.*

849/Individual/Germany/Musical instruments

- *no analytical methods known*
- *No experience with this*

851/DIEHL Metall, Sundwiger Messingwerk GmbH & Co. KG/Germany/Keys

- *Due to the use in dry conditions no lead release from the article.*
- *Any corrosion test for leaching of lead does not represent the practical application of this material.*

852/Individual/Germany Musical instruments

- *So far, we have no experience, because we have neither own measurement options, nor measuring methods are known.*
- *So far, we have no experience, because we have neither own measurement options, nor measuring methods are known.*

853/ALBORCH Y VIDAL S.L/Spain/Curtains and lead weight for fishing industry

- *We made the analysis for the determination of the migration of lead in an accredited laboratory, directly in our lead band, not on curtains that contained it and that are what is really within reach of the general public. The laboratory applied test standard UNE-EN71-3 about Safety in toys, and used an induced plasma emission spectrophotometer. Obtaining an exorbitant lead release rate that clearly does not comply with REACH. Due to this results we decided to make an alternative article with another material without of the scope of REACH, stainless steel. This new article made by stainless steel was subjected to various laboratory studies in saline environments (UNE EN ISO 9227:2012), and we could see that is a completely inert article.*
- *We are aware that our competence (competitors?) has chosen coated the lead band with paint, to solve REACH restrictions; we have serious doubts about whether this is enough to ensure that the lead release rate of the items does not exceed the limit of 0.05 mg / cm² per hour for two years, because the curtains suffer many movements and washes. Furthermore the danger of ingesting lead for children remains because this article contains lead. Having alternative products lead free, lead band for curtains should be banned. We do not know what analytics our competition will have used, but in any case it should be a specific one for that article, which takes into account the normal use of the curtain as well as its successive washes.*

854/Josef Lausmann OHG/Germany/Musical instruments

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- *Our mouthpieces (silver plated and unversilvered) were examined by TÜV Rheinland in accordance with EN 1677-3. The raw material had a lead content of about 3 %. All measurements (silver plated and not silver plated) show that the limit of 0.05 µg / cm² per hour can not be exceeded.*

855/Bundesverband der deutschen Musikinstrumentenhersteller e. V./NGO/Germany/Musical instruments

- *With regard to lead, we have no experience of our own with the corresponding analytical methods.*
- *Due to the need of expensive analyzers, eg. B. mass spectrometer, the methods are available only in professional institutes. Ie. Musical instrument manufacturers can not build up production controls using the method at a reasonable cost. For suitability, we can give no information due to lack of own experience. There are no easy-to-use procedures that can be used in process control in the musical instrument industry.*

856/Wilhelm Heckel GmbH/Germany/Musical instruments

- *We don't have any experience with analytical method*

857/IfM-Institut für Musikinstrumentenbau e.V./NGO/Germany/Musical instruments

- *Identical to nr 855*
- *Identical to nr 855*

858/Japan Electronics and Information Technology Industries Association (JEITA)/Japan/Batteries

- *We don't have any information on the emission test as EEE manufacturers do not conduct an emission test in managing substances in articles. Inclusion test of substances in an article is not mandatory in managing substances in articles under EN IEC 63000 which is harmonized with the RoHS Directive. Moreover, emission test of substances is not mandatory. In the first place, potential exposure to a specific substance depends on the scenario how the article containing the substance is used. Even if the supplier of the materials in the upper stream of the article's supply chain conducts an emission test with the materials, the test result does not always indicate exposure risk of the substance in the finished article as materials itself. Therefore, there is not much point in conducting the emission test. With such reason, we believe that the method stated in IEC 63000, or IEC 692474 is more appropriate to manage substances in articles in global supply chains. EEE manufacturers have complied with restrictions of chemical substances required under applicable legislations such as REACH regulation or RoHS Directive, by setting and implementing its own "Green Procurement Standards" based on the IEC 62474. The example of the list of substances which EEE industry controls can be seen at IEC 62474 database.*
- *Please refer to our comments above. We do not believe that requirement of testing emission would be appropriate for managing substances contained in an article.*

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859/Benedikt Eppelsheim Blasinstrumente/Germany/Musical instruments

- *No experience.*
- *These methods are not part of the manufacturing operation and must be applied by specialized institutes or companies.*

860/Petrof spol. sr.o./Czech Republic/Musical instruments

- *Regarding the lead, we haven't got any experiences with analytical methods.*
- *Our factory is specialized for grand piano and upright piano production. As a middle size company, our RaD centre hasn't got a capacity to look for analytical methods of lead. Because is fully busy by different jobs which are in our opinion more important at this moment.*

861/Metallblasinstrumente/Bernhard Willenberg Company/Germany/Musical instruments

- *I have no experience with methods for determining the release of lead from articles.*
- *At the moment I am not aware of any service providers in this regard. Accordingly, I can not make any statement about the reliability of existing methods.*

862/Individual/Germany/Musical instruments

- *There are no releases as no dust, gases or abrasions occur during processing*
- *The methodology required is financially unaffordable for a sole musical instrument maker*

864/Buffet Crampon Germany GmbH Germany/Musical instruments

- *In the past, we commissioned various external institutes to conduct such investigations. The results varied significant for one batch at the same institute as well as between different institutes. The inaccuracy starts with the 'aging' process (no standard test piece defined) and how many sqcm should be available per fluid container.*
- *Availability is not an issue. As mentioned above the accuracy and reliability of the method has a wide spread (will lead to misinterpretation and 'manipulation')*

865/BORGATO PIANOS/Italy/Musical instruments

- *We have no direct analytic experience with those methods.*
- *We have no direct analytic experience with those methods.*

869/Zirnbauer GmbH/Germany/Musical instruments

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- *We have no experience with the mentioned analytical methods. "We are a small craft business, and we lack the means to use such analytical procedures.*
- *Due to the need of expensive analyzers, eg. B. mass spectrometer, the methods are available only in professional institutes. Ie. Musical instrument manufacturers can not set up production controls using the method at a reasonable cost. For suitability, we can give no information due to lack of own experience. There are no easy-to-use procedures that can be used in process control in music instrument companies."*

871/GEWAmusic/Germany/Musical instruments

- *Long waiting time. Labs do test even stricter than necessary, due to new regulation being in discussion. Although no decision has been settled yet. See issue nickel and the guideline which meant to define "long term contact to skin" While the draft was published lab immediately tested according to stricter rules, as musical instruments were referred to in a sideline. This is a great irritation to the customer!*

872/MASTER MUSIC SRL/Italy/Musical instruments

- *At the moment not many tests have been done on the subject but based on the assumption that lead-containing alloys in our sector have been used for centuries and that no cases have occurred such as to give rise to suspicions, we can affirm with reasonable conviction that lead in our sector it does not harm your health.*
- *Due to the need for expensive analysis tools, e.g. the mass spectrometer, the methods are available only in professional institutes. This means that musical instrument manufacturers cannot set these production controls using the method at a reasonable cost. Regarding eligibility, we are unable to provide information due to lack of direct experience. There are no easy-to-use procedures that can be used in the control of production procedures of musical instrument companies.*

874/WITTNER GmbH & Co. KG/Germany/Musical instruments

- *no analysis feasible*
- *no information possible*

875/Handelsverband Deutschland (HDE)/Germany/Batteries

- *The availability of the test method is considered sufficient to good. On average, the cost of the lead migration test is about twice as high as that of a lead compound content test. In addition, there is the slightly higher expenditure of time. The results are satisfactory in the expectation. So far, no differences were found when articles were made with or without coating.*

876/B.Sandner GmbH&Co.KG/Germany/Musical instruments

- *We have no experiences.*

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- *There are no practicable methods of analysis for musical instrument making.*

877/B+M Textil/Germany Curtains

- *Basically the analysis method 16711-3 is reasonable beside the set limit of 0,05 $\mu\text{g}/\text{cm}^2$ per hour as mentioned above. There are several efforts to really see if the analysis approach leads to reproduceable results. A volunteer group of German analysis laboratories plan to perform a circle analysis to compare the results of a set of normal products.*
- *The analysis method 16711-3 is just published and maybe can solve the big questionmarks and insecurities about product applications in the market. Setting up a limitation without a usefull analysis method is really completely nonsense and just producing difficulties. Maybe there is a group of people out there establishing rules that really make sense and bring up a cleared, evaluated and working set of conditions before publishing.*

878/European Copper Institute (ECI)/Belgium

- *Keys, locks and padlocks "The European Copper Institute doesn't have experience in testing final products produced using copper alloys with coated or otherwise treated surfaces. Nor does ECI have any experience with methods and procedures to simulate wear in coatings, like EN 12472. The reason for this is that ECI's function is to represent the European copper producing and fabricating (semis / bulk material) industry rather than the downstream industry. Therefore, and aiming at achieving reproducible and repeatable metal release rates from bulk materials, the European Copper Institute in the past developed a test method and performed several investigations on lead migration, particularly from lead containing brasses but also from other alloy families, like lead containing nickel silver (which is an alloy containing primarily copper, nickel and zinc) . The tests were performed in artificial saliva media (to simulate mouthing, which is the main source for Pb uptake from consumer products) as well as in artificial gastric media (to simulate swallowing). The results of these investigations were submitted to ECHA in the course of the public consultation during the drafting of the regulation in 2013 and published afterwards in 2014. The results indicated, that the lead migration rate in saliva might exceed the limit value of 0,05 $\mu\text{g Pb}/\text{cm}^2/\text{h}$ given a lead content in the alloy of above 0.5 % (m/m). For technical reasons, a number of copper alloys (brasses and nickel silvers) are used for the production of keys, locks and musical instruments, and these need to have Pb contents above 0,5 % (w/w) in order to fulfill basic material functions. Lead free or Pb reduced materials, developed in the meantime, are under approval for a series of applications but unfortunately, in the context of this paper, do not yet deliver satisfying results for intended uses. This reasoning will be dealt with in detail later in this paper but it can clearly be stated at this stage, that a renewal of the exemption for the above mentioned product groups is still needed.*
- *As written above, ECI's experience is NOT in the analytical methods in use.*

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ELF - European Locksmith Federation/Finland/Locks

- *ELF does not have any experience with analytical methods for determining that the rate of lead release from articles (coated or uncoated) does not exceed the limit of 0.05 micrograms/cm² per hour. Nevertheless, ELF is aware about a respective test method developed by the European Copper Institute (ECI) which focuses on semi-finished products but not on articles like keys, lock cylinders and padlocks*
- *This question cannot be answered as neither ELF nor the national associations and also not the individual locksmiths have any know-how and experience with such methods*

7.5. Annex 4: The relationship of lead migration and content measured per EN 16711-3

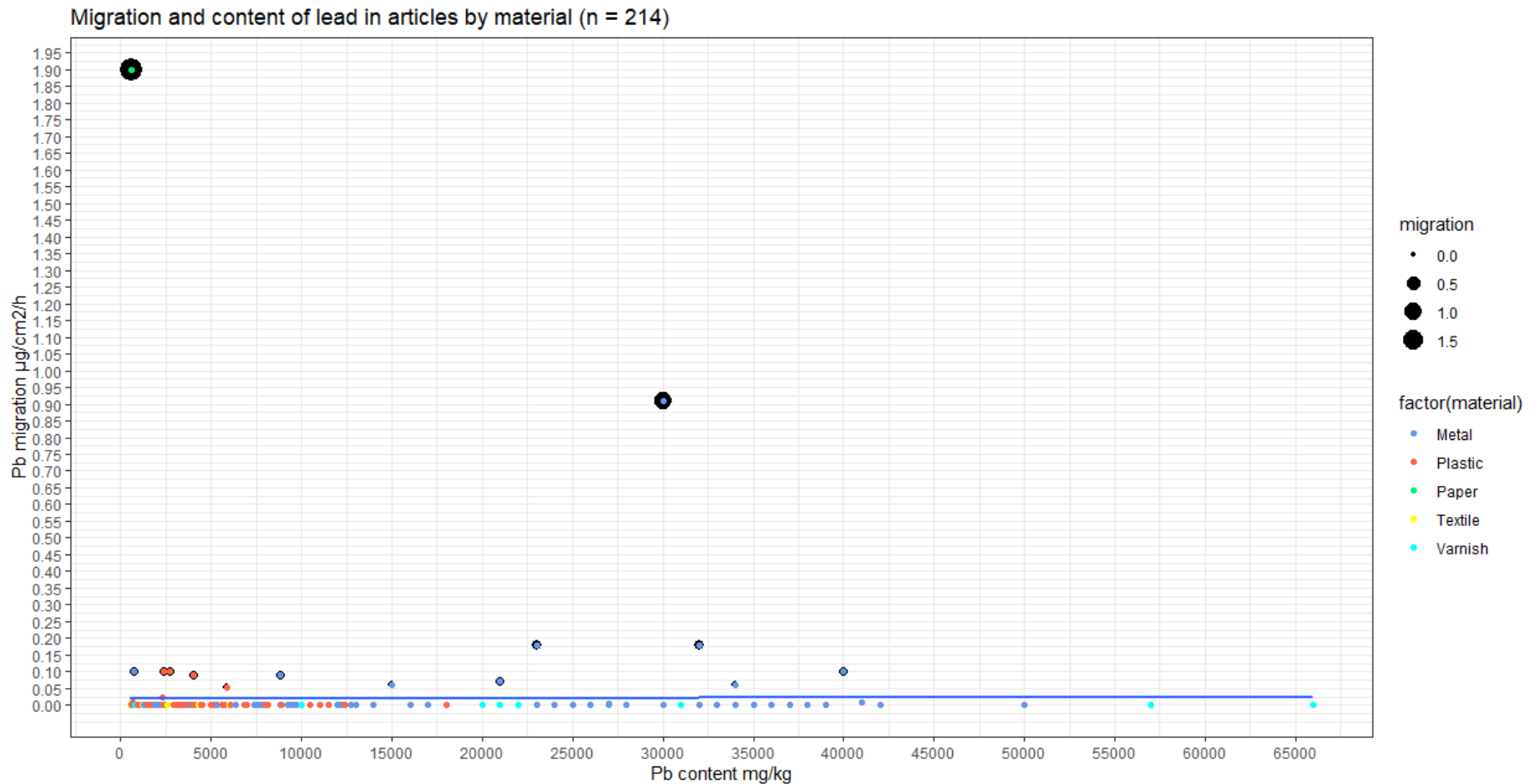


Figure 7: Relationship between lead content and migration in articles of different material types. Data received from Tuv Rheinland. One observation of migration below the detection limit at 22 % content of lead (presenting the maximum value for content) removed for clarity.