Exemption Request Form ROHS- Exemption 6b II

Date of submission: 09 October 2020

1. Name and contact details

1) Name and contact details of applicant:

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On behalf of the Company/Business organisations/Business associations listed below participants in the **RoHS Umbrella Industry Project ("the Umbrella Project"):**

The European Automobile Manufacturers' Association (ACEA) EU Transparency Register ID number: 0649790813-47	American Chamber of Commerce to the European Union (AmCham EU) EU Transparency Register ID number: 5265780509-97	ANIE Federation EU Transparency Register ID number: 74070773644-23	Communications and Information Network Association of Japan (CIAJ)
Copper Development Association Inc. (CDA)	DIGITALEUROPE (DE) EU Transparency Register ID number: 64270747023-20	European Association of Internal Combustion Engine Manufacturers (EUROMOT) EU Transparency Register ID number: 6284937371-73	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) EU Transparency Register ID number: 05366537746-69
European Garden Machinery Industry Federation (EGMF) EU Transparency Register ID number: 82669082072-33	European Partnership for Energy and the Environment (EPEE) EU Transparency Register ID number: 22276738915-67	European Passive Components Industry Association (EPCIA) EU Transparency Register ID number: 22092908193-23	The European Semiconductor Industry Association (ESIA) is an industry association working under the umbrella and legal entity of the European Electronic Component Manufacturers Association (EECA) EU Transparency Register ID number: 22092908193-23
Fédération des Industries Mécaniques (FIM) EU Transparency Register ID number: 42858181373783-89	GAMBICA - The UK Association for Instrumentation, Control, Automation & Laboratory Technology	Gesamtverband der Aluminiumindustrie e.V. (GDA) EU Transparency Register ID number: 654963534726-10	Information Technology Industry Council (ITI) EU Transparency Register ID number: 061601915428-87
Interconnect Technology Suppliers Association (ITSA)	IPC International, Inc. EU Transparency Register ID number: 390331424747-18	Japan Analytical Instruments Manufacturers' Association (JAIMA)	Japan Business Council in Europe (JBCE) EU Transparency Register ID number: 68368571120-55

Japan Business Machine and Information System Industries Association (JBMIA)	Japan Electric Measuring Instruments Manufacturers' Association (JEMIMA)	Japan Electrical Manufacturers' Association (JEMA)	Japan Electronics and Information Technology Industries Association (JEITA)
Japan Federation of Medical Devices Associations (JFMDA)	Japan Inspection Instruments Manufacturers' Association (JIMA)	Japan Land Engine Manufacturers Association (LEMA)	Japan Lighting Manufacturers Association (JLMA)
Japan Measuring Instruments Federation (JMIF)	Japan Medical Imaging and Radiological Systems Industries Association (JIRA)	LightingEurope (LE) EU Transparency Register ID number: 29789243712-03	MedTech Europe EU Transparency Register ID number: 433743725252-26
Nippon Electric Control Equipment Industries Association (NECA)	SPECTARIS - German Hightech Industry Association EU Transparency Register ID number: 55587639351-53	The Japan Auto Parts Industries Association (JAPIA)	Wirtschafts Vereinigung Metalle (WVMetalle) EU Transparency Register ID number: 9002547940-17
Wirtschaftsverband Großhandel Metallhalbzeug e.V. (WGM)	Wirtschaftsverband Industrieller Unternehmen Baden e.V. (wvib)	Wirtschaftsverband Stahl- und Metallverarbeitung e.V. (WSM) EU Transparency Register ID number: 921351835520-23	ZVEI - German Electrical and Electronic Manufacturers´ Association EU Transparency Register ID number: 94770746469-09

2. Reason for application:

Please indicate where relevant:

☐ Request for new exemption in:

☐ Request for amendment of existing exemption in

☒ Request for extension of existing exemption in

☐ Request for deletion of existing exemption in:

☐ Provision of information referring to an existing specific exemption in:

☒ Annex III ☐ Annex IV

No. of exemption in Annex III or IV where applicable: 6 (b) II

Proposed or existing wording: existing wording ‘Lead as an alloying element in aluminum for machining purposes with a lead content up to 0,4 % by weight ‘

Duration where applicable: *We apply for renewal of this exemption for the category marked in section 4 further below for the maximum validity period foreseen in the RoHS2 Directive, as amended. For this category, the validity of this exemption may be required beyond those timeframes. As specified in separate requests to renew the exemption submitted to the European Commission within the deadline foreseen by the Directive for submission of applications, applications in this exemption renewal request are relevant to other categories not marked in section 4 further below.*

☐ Other: _____

3. Summary of the exemption request / revocation request

The purpose of lead in aluminum alloys is to improve machinability without influence on mechanical properties. Lead acts as a lubricant and results in better chip fracturing and surface finish and allows higher cutting speeds and a longer tool life. Previous exemption request submissions reduced the allowed lead content from 1% for machinability down to 0,4%. The main reason for ability to reduce lead content was improved machines with much higher cutting speeds and new tools like DLC coated or CVD protected blades. Since the last renewal from 2015 no significant machine improvements were able to be introduced, with the focus from industry turning to different alloy types.

This renewal request is based on the fact that only a very low amount of leaded aluminum is still required for some niche applications. In some niche application the total time period between availability of a new material and the type or application approval of the final machine takes a very long time period. Hence it isn’t possible in the time frame of a single exemption period to substitute the material.

As a substitute for lead, the element bismuth is used for a wide range of leadfree alternatives but the environmental impact of bismuth is even worse than lead and, therefore, ecologically not appropriate.

Tin is available as a substitute for lead in only one aluminium alloy and, therefore, is not available as an alternative for a wide range of applications.”

4.Technical description of the exemption request / revocation request

(A) Description of the concerned application:

1. To which EEE is the exemption request/information relevant?

Name of applications or products: All weight sensitive technical applications for EEE. An exhaustive list cannot be provided due to the diverse nature of the end products which utilise components with aluminium containing lead.

List of relevant categories: (mark more than one where applicable)

☐ 1	☐ 7
☐ 2	☐ 8
☐ 3	☐ 9
☐ 4	☐ 10
☐ 5	☒ 11
☐ 6	

a. **Please specify if application is in use in other categories to which the exemption request does not refer:** *As specified in separate requests to renew the exemption submitted to the European Commission within the deadline foreseen by the Directive for submission of applications, applications in this exemption renewal request are relevant to categories not marked above and below.*

b. Please specify for equipment of category 8 and 9:

The requested exemption will be applied in

☐ monitoring and control instruments in industry

☐ in-vitro diagnostics

☐ other medical devices or other monitoring and control instruments than those in industry

2. **Which of the six substances is in use in the application/product?**
   (Indicate more than one where applicable)

   ☒ Pb ☐ Cd ☐ Hg ☐ Cr-VI ☐ PBB ☐ PBDE

3. **Function of the substance:** The main effect of lead is improved machinability. Lead acts as a lubricant to enable smooth surfaces without flow marks on the machined surface, better chip fracturing to keep swarf short, and less mechanical stress remaining in the machined parts.
4. **Content of substance in homogeneous material (%weight):** up to 0,4%

5. **Amount of substance entering the EU market annually through application for which the exemption is requested:** about 90 tonnes of lead
6. **Please supply information and calculations to support stated figure**. see Section 5 (3) for calculations

7. **Name of material/component:** Aluminium alloy containing lead

8. **Environmental Assessment:** _____
   LCA: ☐ Yes
   ☒ No

(B) In which material and/or component is the RoHS-regulated substance used, for which you request the exemption or its revocation? What is the function of this material or component?

Lead in the alloys improves technical characteristics such as:

- Micro-machining;
- Electrical conductivity;
- Galvanic corrosion prevention;
- Improves corrosion resistance. Corrosion of medical devices can be an issue if they may need to be chemically sterilised or can be contaminated with body fluids. Similarly, monitoring equipment in hostile environments would also be exposed to corrosive substances.
- Mechanical relaxation;
- Tribological behavior;
  - Superior machinability due to factors such as chip fracturing and surface finish. During cutting process of aluminum thick swarf of minimum 0,1mm need to be cut to prevent high stress and temperature induced during machining which is too much for high precision machining. In particular for soft aluminum alloys this effect is significant because too high stress/force during cutting process

increases the temperature into the part and lead to an uncontrolled annealing with negative influence on the material properties;
    - Enhanced tool lifetime;
    - Better wear resistance of components as it reduces friction and wear of surfaces that slide against others (such as connectors); and
- Ability to form lightweight, intricate shape parts. A key driver for precision machined parts is the requirement of very small and light weight designs forced by the desired function. Upcoming new light weight applications with motion control for autonomous motion and prosthesis are relevant for the future.

Aluminium alloys containing lead are used to make parts and components including Mechanical structures with sliding elements or a requirement for electrical or heat sink functions e.g. in end effectors of handling systems;

- Frameworks and equipment housings that need to be machined to precise shapes and dimensions in complex electromechanical gears e.g. tools and parts which need to be used in fluorinated or chlorinated gas ambient like chemical vapor treatment for semiconductor processes or chemical surface treatment;
- Precision machined frame of body-parts of handheld tools
- Metal knobs (of switches), connector bodies, terminals, crimp connectors, cable glands, pipe fittings, nuts, hooks, eyelets, etc.;
- Platens and hard masks for CVD evaporation in fluoric ambient with local high temperature gradients and no allowed distortion; and
- Electrical components that have variable functions that are adjusted using screws having very precise dimensions made from leaded aluminium alloys, e.g. variable inductors.
- Precision machined flow meters for marine applications. Lead additive in aluminium alloys has been found to be essential in high accuracy machining for explosion proof enclosures and lead has also been found to improve corrosion resistance which is crucial especially in near-shore or off-shore marine applications. Aluminium alloys are especially susceptible to corrosion in wet chloride environments, but lead effectively reduces corrosion rate.

(C) What are the particular characteristics and functions of the RoHS-regulated substance that require its use in this material or component?

The main effect of lead is an improved machinability. Lead acts as a lubricant and the addition of lead results in better chip fracturing and surface finish as well as in higher cutting speeds and a longer tool life, which are desirable from both energy saving and material use point of view.

5. Information on Possible preparation for reuse or recycling of waste from EEE and on provisions for appropriate treatment of waste

1) Please indicate if a closed loop system exist for EEE waste of application exists and provide information of its characteristics (method of collection to ensure closed loop, method of treatment, etc.)

The closed loop system for aluminium in Europe is based on legal requirements and commercial profits, but no specific "closed loop" for aluminium parts of electrical equipment exists.

2) Please indicate where relevant:

☒ Article is collected and sent without dismantling for recycling

☒ Article is collected and completely refurbished for reuse: applicable to some types of electrical equipment including some types of medical device such as CT and MRI

☐ Article is collected and dismantled:

- ☐ The following parts are refurbished for use as spare parts: _____
- ☐ The following parts are subsequently recycled: _____

☐ Article cannot be recycled and is therefore:

- ☐ Sent for energy return
- ☐ Landfilled

3) Please provide information concerning the amount (weight) of RoHS substance present in EEE waste accumulates per annum:

☐ In articles which are refurbished _____

☒ In articles which are recycled: The majority of aluminium is recycled, with estimated figures for lead containing aluminium in industrial sectors as high as 99.7%. The calculations utilised to come to this figure are outlined below.

☐ In articles which are sent for energy return _____

☐ In articles which are landfilled _____

The majority of aluminium is recycled, with the total aluminium rate collection for transportation, industrial and construction equipment is reported to be greater than 90%. As there are no detailed figures available for the amount of lead containing aluminum recycling rate, below details estimated figures as the associated assumptions utilized to obtain a figure based on several internet publications.

In Europe about 7,7 million tonnes of Aluminum were produced in 2018[1]. Assuming that about 4,5 million tonnes are in industrial sectors, out of this (based on statistical assumptions) about 450000 tonnes (10%) is not recycled.

However, not all of these applications would contain lead up to 0,4%, assuming that 5% of the unrecycled material includes lead up to 0,4% results in 22500 tonnes of aluminium containing lead. Consequentially, this would result in 90 tonnes of lead which is not recycled. In the overall scheme this will have minimal impact as it results in 0,3% of the EU total aluminium production.

Considering applications which are out of scope (e.g. military or space applications), which probably have a much higher content of lead containing applications. The above mentioned figure of 90 tonnes of lead will be further reduced but is unable to be calculated. The actual total is probably considerably less than 90 tonnes per year but it is not possible to determine this amount.

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6. Analysis of possible alternative substances

(A) Please provide information if possible alternative applications or alternatives for use of RoHS substances in application exist. Please elaborate analysis on a life-cycle basis, including where available information about independent research, peer-review studies development activities undertaken

Generally chip breaking alloying element have to show the following properties:

a) The element is insoluble in solid aluminum;

b) Lower melting point in comparison to aluminum

c) Do not form intermetallic compounds with aluminum or other alloying component; and

d) Have a lower hardness than the aluminum matrix.

Low melting point metals such as tin and cadmium are sometimes used to aid machining as they exhibit a restricted solubility in solid aluminum and form a soft, low-melting phase that promotes chip breaking and helps to lubricate the cutting tool. Cadmium is similarly toxic to lead and is also RoHS-restricted and hence cannot be used as a substitute to lead.

Bismuth has been investigated as an alternative. However, it is a critical raw material as defined by from the European Commission in 2017. The current production of bismuth is linked to the production of lead as a byproduct. Therefore, if the usage of lead were to decline in the future, production rates of bismuth would

[1] http://www.world-aluminium.org/statistics/primary-aluminium-production/#map

be impacted. More than 80% of bismuth is mined and produced in China. Additionally, the total negative environmental and health impacts of bismuth, compared with lead need to be considered and can be compared using data from a published Life Cycle Assessment:

In some alloys Tin is used as a substitute to Lead often in combination with Bismuth. However, in turning and machining tests long and continuous stripes were observed[2] which cause very poor machinability.

Table 1 Bismuth and lead metal environmental and health impacts[3]

Impact	Units	Lead	Bismuth	Bismuth / lead ratio
Human toxicity	CTUh/kg	0.0000099	0.000017	1.72
Fresh water eutrophication	kgP-eq/kg	0.0022	0.022	10.00
Cumulative energy demand	MJ eq/kg	18.9	697	36.88
Terrestrial acidification	kg SO2 eq/kg	0.028	0.38	13.57
Global Warming Potential	kg CO2-eq/kg	1.3	58.9	45.31

The data outlined in Table 1 outlines the burdens of elemental lead and bismuth production on the basis of a functional unit of 1kg at the factory gate following the ISO 14040 and 14044 standards. However, the boundaries of the analysis in the study referred to in footnote 2, are such that it does not consider the manufacture or disposal of aluminium alloys containing lead or bismuth.

- Manufacture of alloy parts – lead and bismuth are both added to aid machinability as explained below and so the impact on energy consumption may be similar, but this is not certain for some applications with bismuth additive;
- Use phase – no difference in impacts; and
- End of life – As explained below, bismuth additive can negatively affect recycling of aluminium alloys, whereas aluminium alloys containing lead are widely used where the lead is not detrimental (and is permitted by exemption 6bI).

Over the entire life cycle of electrical equipment, it is clear that lead as an additive has a less negative overall health and environmental impact than bismuth.

The manufacturability of bismuth alloys for some alloy types is similar to lead containing alloys[4,5] however to fully understand the quality of a machined surface

[2] *Influence of tin and bismuth on machinability of lead free 6000 series aluminium alloys", G. Timelli et al., Materials Science and Technology, Jan. 2011*

[3] *//www.ncbi.nlm.nih.gov/pmc/articles/PMC4085040/*

[4] *https://www.tandfonline.com/doi/abs/10.1179/026708309X12595712305799?src=recsys&journalCode=ymst20*

[5] *https://www.researchgate.net/publication/235998034_The_Influence_of_Bismuth_Antimony_and_Strontium_on_Microstructure_Thermal_and_Machinability_of_Aluminum-Silicon_Alloy/link/02e7e52b65de25f41c000000/download*

after machining it is essential to know for each alloy type the microstructure which has not been fully investigated for all alloys and uses. Mixed scrap of bismuth containing and lead containing scrap causes negative effects in the waste stream[6] and might increase the waste to be landfilled[7]. In comparison, there is a closed loop material system for lead containing aluminium alloys.

Tin (Sn) is reported by multiple manufacturers[8,9] as causing cracking in machined parts when subjected to stress and high temperature. It is also reported that small quantities of tin in some alloy types will cause surface darkening on annealing and increase the susceptibility to corrosion[10]. These affects can be reduced by addition of other alloying elements (such as lead). The majority of commercially available alloys, detailed in Table 4, contain bismuth in addition to tin and therefore the environmental and health impacts of bismuth would have to be considered. The exception to this is the alloy 6020 which is the sole commercially available aluminium alloy containing tin but not lead or bismuth.

In addition to the technical impact of tin, it is a conflict material and the total negative environmental, societal, and health impacts of tin need to be considered:

Table 2 Tin and lead metal environmental and health impacts[3]

Impact	Units	Lead	Tin	Tin/Lead Ratio
Human toxicity	CTUh/kg	0.0000099	0.000006	0.606060606
Fresh water eutrophication	kgP-eq/kg	0.0022	0.012	5.454545455
Cumulative energy demand	MJ eq/kg	18.9	321	16.98412698
Terrestrial acidification	kg SO2 eq/kg	0.028	0.43	15.35714286
Global Warming Potential	kg CO2-eq/kg	1.3	17.1	13.15384615

The data outlined in Table 2 follows the same methodology and boundaries of analysis as Table 1. On all aspects of measurement, with the exception of human toxicity, tin has a higher impact than lead and, therefore, is not a viable alternative on the basis of the total negative health and environmental benefits of substitution do not outweigh the benefits of substitution.

The above comparison of life cycle impacts of lead and tin is less clear than the lead with bismuth comparison because not all impacts of tin are more negative than lead. However, as explained below in section 7 (A), the reliability of aluminium tin alloys is not ensured.

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[6] *https://copperalliance.eu/uploads/2018/01/bismuthnonsuitability3c80c8107bd124e19f48e60e.pdf*

[7] *Similar negative effects occur when bismuth-containing scrap is mixed unintentionally with bismuth-free scrap*

[8] https://www.smithmetal.com/6026.htm

[9] http://www.aalco.co.uk/datasheets/Aluminium-Alloy-6026-T9-Rod-and-Bar_143.ashx

[10] https://materialsdata.nist.gov/bitstream/handle/11115/173/Aluminum%20and%20Aluminum%20Alloys%20Davis.pdf?sequence=3&isAllowed=y

There are some alloy compositions including beryllium which is used in some applications. However beryllium is similarly toxic to lead and the global mine production in 2018 was only 230 tonnes[11] which is not sufficient to meet the demand of 90 tonnes of lead required in this application.

In summary there is no suitable alternative as outlined in Table 3.

Table 3 Overview of potential alternative analysis

Potential alternative	Rationale for determination of unsuitability
Cadmium	RoHS restricted; REACH-SVHC; negative environmental and health impacts
Bismuth	Total negative environmental and health impacts in mining and at refining stage
Tin	Reliability and social critical mining; very limited mechanical properties
Beryllium	Similar toxicity to lead and limited availability of alternative

(B) Please provide information and data to establish reliability of possible substitutes of application and of RoHS materials in application

For some uses, reliability may not be an issue, but when a material is changed this may require some products to be requalified. For example in a medical device, the manufacturer is obliged by the Medical Devices Regulation to assess this change to determine if it could affect reliability as well as the safety of patients and hospital workers. Re-approval by a Notified Body may also be required.

[11] https://s3-us-west-2.amazonaws.com/prd-wret/assets/palladium/production/mineral-pubs/mcs/mcs2018.pdf

7. Proposed actions to develop possible substitutes

(A) Please provide information if actions have been taken to develop further possible alternatives for the application or alternatives for RoHS substances in the application.

The aluminium industry, together with its downstream industries, have been finding and testing lead free alloys. A non-exhaustive list based on availability of compositional data in literature[12] is listed in Table 4.

Table 4 Maximum concentrations of alloying elements in some lead free alloys

Alloy	Bi %	Pb %	Sn %
2111	0.2-0.8	0	0.1-0.5
2012	0.2-0.7	0	0.2-0.6
2111A	0.2-0.6	0.05	0.2-0.6
2028C	0.4-1.0	0.05	0.2-1.0
2111B	0.3-0.6	0	0.3-0.7
2041	0.5-0.7	0.05	0.5-0.7
2044	0.2-0.40	0.05	0.9-1.3
2045	0.2-0.4	0.05	0.9-1.3
6026 LF	0.5-1.5	0	0.05
6033	0.30-1.0	0.05	0
6065	0.50-1.5	0.05	0
6040	0.15-0.7	0	0.3-1.2
6041	0.30-0.9	0	0.35-1.2
6262A	0.4-0.9	0	0.4-1.0
6012A	0.7	0	0.4-2.0
6028	0.6-0.8	0	0.6-0.8
6020	0	0.05	0.9-1.5
6023	0.3-0.8	0	0.6-1.2

The majority of lead-free aluminium alloys predominantly rely upon bismuth, with the exception of 6020 which relies upon tin. The lack of availability of bismuth and lead free aluminium alloys would support the assessment that the technical performance of tin alloys is not as closely matched to the traditional lead containing aluminium alloys. Due to the rationale as outlined by Section 6(A) these are not suitable alternatives.

Device manufacturers are reliant on aluminium alloy manufacturers to develop substitute lead-free machining alloys which contains less or no lead. In its request to renew exemption 6b in 2015, the European Aluminium Association stated that

[12] *https://european-aluminium.eu/media/1343/international-alloy-designations-and-chemical-composition-limits-for-wrought-aluminum-and-wrought-aluminum-alloys.pdf*

at present no suitable alternatives exist. Due to the majority of currently identified lead free alloy containing bismuth, with its associated environmental and health impact, the same statement of no suitable alternatives existing is as true for this application as it was for the previous application.

In recognition of this investigations into alternatives have started to occur. One such example is aluminium foam compositions, without the inclusion of lead in the alloy, currently are being researched to investigate light weight applications. So far, they are far away from industrial standards for design of complex structures. Up to now only sheets are available by a few suppliers.

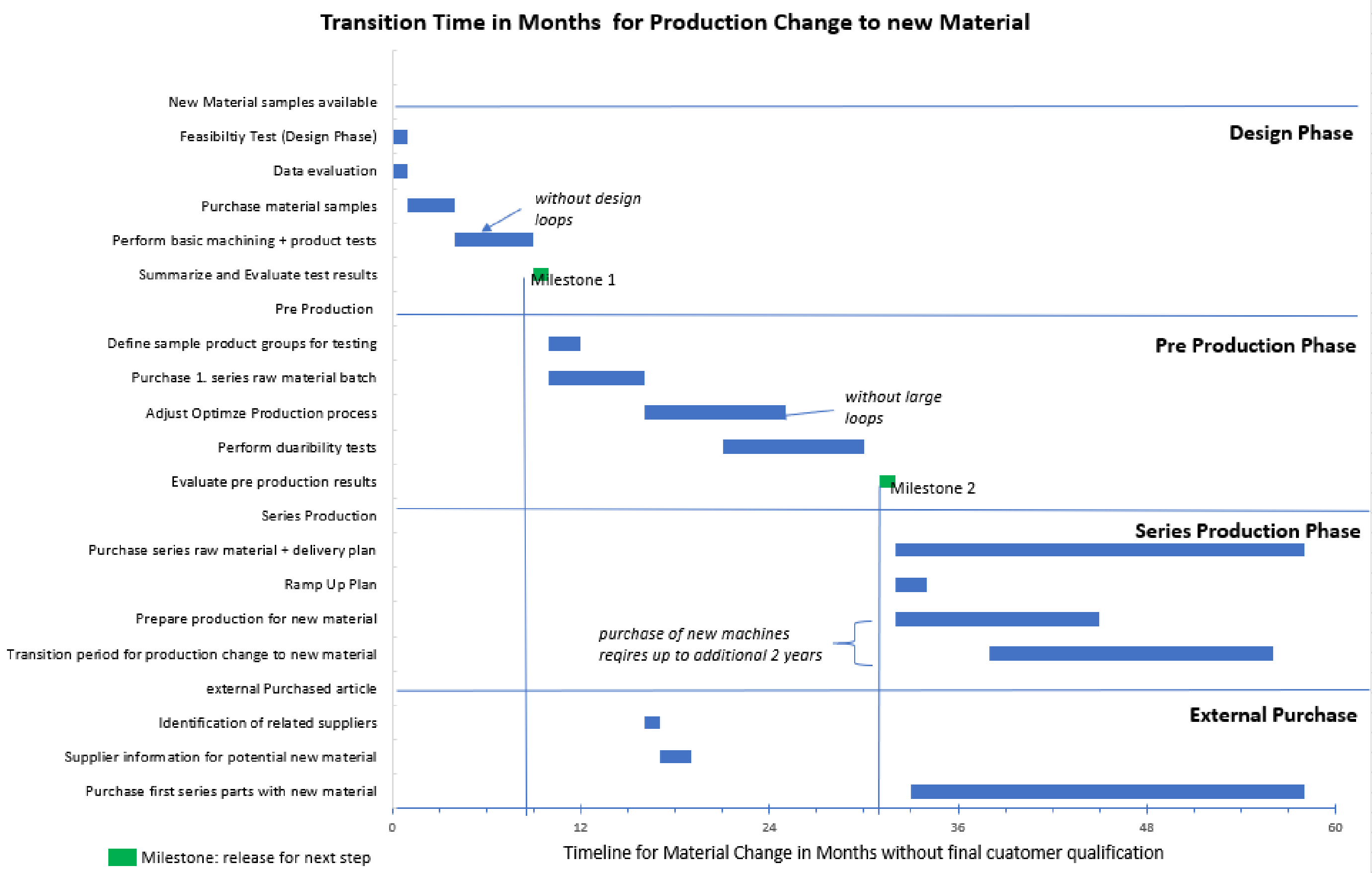
Lead free aluminium die cast alloys with good precision machining capabilities like EN AC43400 and EN AC 6026 still need to rely on lead. The lead free and Bismuth containing substitute AW 2660LF is not capable for die casting.

(B) Please elaborate what stages are necessary for establishment of possible substitute and respective timeframe needed for completion of such stages.

Alloys should be developed and readily available with the suitable combination of characteristics.

Starting point for this approach is the availability of a new material in samples from the material manufacturer and it ends at transition of the whole production of to the new material of a medium size company. The overall time takes about 5 year in optimistic calculations. This is only possible in case no general design loops are necessary, sufficient qualification capacity is available, and no new machining tools need to be bought. Depending on the tool complexity lead time is up to 2 years delivery time which needs to be added to the total time frame. As well necessary qualifications at customer level are not taken into account, because these qualifications strongly depend on the dedicated legal and market requirements.

Table 5 Typical timescales of production change to new material



Medical device redesign due to the incorporation of lead-free alloys would require testing to ensure the substitute meets the same performance requirements before they can be evaluated using clinical trials. Once these trials are successfully completed, Notified Body approval in the EU and the equivalent approvals globally can be requested. Typical timescales would be once a suitable alternative becomes available for testing is outlined in Table .

Table 6 Typical timescales of the redesign of a medical device

Test	Timeframe
Testing of alternative alloy	6 months
Testing of component made with new alloy	6 months
Redesign of the component/device (reasonable that minor changes are required)	12 months (redesign + retesting)
System performance and reliability testing	1 year
Global approvals	Up to 2 years
Total elapsed time	About 5 years but only if alloy passes all tests and is suitable

These examples demonstrate a transition time of up to 10years to bring a new material into critical markets like the medical one.

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8. Justification according to Article 5(1)(a):

(A) Links to REACH: (substance + substitute)

1) Do any of the following provisions apply to the application described under (A) and (C)?

   ☐ Authorisation

   - ☐ SVHC
   - ☐ Candidate list
   - ☐ Proposal inclusion Annex XIV
   - ☐ Annex XIV

   ☐ Restriction

   - ☐ Annex XVII
   - ☐ Registry of intentions

   ☐ Registration

2) Provide REACH-relevant information received through the supply chain.
   Name of document:

Based on the current status of Annexes XIV and XVII of the REACH Regulation, the requested exemption would not weaken the environmental and health protection afforded by the REACH Regulation. The requested exemption is therefore justified as other criteria of Art. 5(1)(a) apply

(B) Elimination/substitution:

1. Can the substance named under 4.(A)1 be eliminated?

   ☐ Yes. Consequences?

   ☒ No. Justification: Negative environmental and health impact as well as inferior performance (dimensional precision and surface finish) and reliability. See Section 6 for justification.

2. Can the substance named under 4.(A)1 be substituted?

   ☐ Yes.

   ☐ Design changes:

   ☐ Other materials:

   ☐ Other substance:

   ☒ No.

   Justification: Some alloys have been substituted by lead free compositions like e.g. AW-6026 to AW-6026LF as lead free alternative with high bismuth content. However this is not possible for all applications currently.

3. Give details on the reliability of substitutes (technical data + information): See section 6(A). With the exception of some automotive applications no information on reliability for industrial purpose is available. Until all applications are able to trial lead free alloys then the reliability is not ensured. This is of particular important to safety critical devices such as medical devices where a design change can require lengthy testing and Notified Body approval.

4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to

1) Environmental impacts: For full information refer to Section 6
   - Bismuth is rated as Critical Raw Material form the EU;
   - The total negative environmental and health impacts of bismuth use as a substitute is higher than that of lead as outlined in Table 1;
   - The current generation of bismuth is linked to the production of lead as a by-product, therefore the production rates of bismuth are unlikely to be able to support the total transition from lead to bismuth;
   - Mixed scrap of bismuth containing and not bismuth containing scrap causes negative effects in the waste stream and might increase the waste to be landfilled; and
   - If beryllium was to be used as a substitute, beryllium is similarly toxic to lead and would have the same environmental impact.
2) Health impacts: _____
3) Consumer safety impacts: Consumers safety would be negatively impacted if this exemption were not renewed and safety critical devices such as medical devices were not available in the EU as a result.
   As complex end products invariably have global supply chains which include non-EU entities, if the exemption was not to be granted, the safety roles the items perform would not be able to be satisfied within the EU.

⇨ Do impacts of substitution outweigh benefits thereof? Yes, see section 6
Please provide third-party verified assessment on this: See footnote 3

(C) Availability of substitutes:

a) Describe supply sources for substitutes: The potential alternative of bismuth is a critical raw material and is a by-product of lead mining. There may be concerns over its production were primary lead manufacture to be reduced.

b) Have you encountered problems with the availability? Describe: About 80% of bismuth mining comes from regions in China and hence could pose an availability issue

c) Do you consider the price of the substitute to be a problem for the availability?

☒ Yes ☐ No

Currently bismuth is 7 to 17 times more expensive than lead. Furthermore, if the demand for bismuth increases and the demand for lead decreases, the price of bismuth may become even higher.

d) What conditions need to be fulfilled to ensure the availability? _____

(D) Socio-economic impact of substitution:

⇨ What kind of economic effects do you consider related to substitution?

☒ Increase in direct production costs, in applications where machinability is the reason for lead, lead-free alloys (if they were to exist) may require more energy, cause greater tool wear and create more scrap. Bismuth is around 7 to 17 times more expensive than lead. Furthermore, if the demand for bismuth increases and the demand for lead decreases, the price of bismuth may become even higher

☒ Increase in fixed costs

☐ Increase in overhead

☒ Possible social impacts:

- Within the EU new modern high technologies like semiconductor, mobile devices, endoscopic surgery or functional prothesis rely on international supply chain. This means the parts are not designed in the EU, but functional devices are bought from outside EU. The users of these devices have no control and influence on the materials used for the sub devices. The European market for these new technologies is too small to influence the design reliably. Therefore, if the exemption is not renewed, then other industrial leading countries may benefit from the new technology niches that EU countries may not be able to use.

  One example of significant impact of this would be the semiconductor industry which has almost no tool suppliers located in Europe, with all suppliers moving to either Asia or the United States. The result of no exemption would lead to Europe being cut off from significant new developments.

- EU patients' health would be negatively impacted if this exemption were not renewed and new medical devices were not available in the EU as a result

☐ Possible social impacts external to the EU

☐ Other: _____

⇨ Provide sufficient evidence (third-party verified) to support your statement: The metal prices are published up-to-date on the internet as well as by LME, etc.

9. Other relevant information

Please provide additional relevant information to further establish the necessity of your request:

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10. Information that should be regarded as proprietary

Please state clearly whether any of the above information should be regarded to as proprietary information. If so, please provide verifiable justification:

References: