**General comments and answers to specific information requests**

**Specific information requests:**

1. SEAC’s view is that a transition period of 7 years for the entry into force of the ban of the use of the substances in metalworking fluids is required since alternatives may not be readily available for all extreme pressure metalworking fluid applications. SEAC also notes that several respondents who contributed to the third-party consultation of the Annex XV restriction report requested a transition period longer than 7 years. However, SEAC’s view is that these requests were not sufficiently substantiated.

SEAC is therefore looking for additional information on the use of the substances in metalworking fluids that would allow SEAC to further assess whether a longer transition period for these applications is needed. In abscence of concrete and well substantiated comments, SEAC will consider that the conclusion reached on the transition period required for the use in metalworking fluids is adequate.

1. The third-party consultation of the Annex XV restriction report confirmed that substances containing chloroalkanes with carbon chain lengths from C14 to C17 which are used as extreme pressure additives in metalworking fluids for heavy duty metal working operations (such as fine blanking, broaching and deep drawing) are challenging to replace with alternatives and that it seems that the type of fluids concerned are oil-based fluids. Based on this, the Dossier Submitter has refined the wording of the derogation for metalworking fluids under restriction option B in the Background Document to specify the type of fluids that should be covered by the derogation, namely oil-based metalworking fluids as defined under DIN 51385.

However, SEAC is concerned that the wording of the scope may be too narrow, as other categories of metalworking fluids (not covered by the definition of oil-based fluids under this DIN standard) might also be relevant and should be included under paragraph 8 of the restriction entry text.

Please provide detailed information on whether other categories of metalworking fluids used for heavy-duty applications and not covered by DIN 51385 would also require a longer transition period than 2 years. Please refer to any relevant industry standards applicable to the type of metalworking fluids concerned.

1. According to the SEAC draft opinion, a ban on the manufacture of the substances within the scope of the restriction proposal should enter into force after the 7-year transition period for metalworking fluids has ended. Please, provide further information on the potential impacts of a ban on manufacturing, once the ban on the placing on the market and use of the substance in the EU has entered into force.
2. During the third-party consultation on the Annex XV report, some stakeholders have indicated the presence of substances containing chloroalkanes with carbon chain lengths from C14 to C17 in concentrations above 0.1% (and up to 15%) in PVC recyclates (e.g. from PVC cables) and PVC articles made of these PVC recyclates. According to the recently published restriction on Pb in PVC , flexible PVC containing Pb above 0.1% by weight will no longer be allowed to be recycled in Europe by 28 May 2025. In this context, SEAC would like to understand how the restriction on Pb in PVC would affect the recycling of PVC containing chloroalkanes with carbon chain lengths from C14 to C17. Please estimate the quantity/volume of recycled PVC that would not contain Pb but could still contain chloroalkanes in the scope of the restriction proposal.

**SEAC rapporteurs’ response to comments on spare parts in automotive sector and EEE (Electrical and Electronic Equipment)**

Several comments were provided requesting a permanent derogation for legacy spare parts.

These requests were mainly from the automotive sector (automotive covering all land-based vehicles, such as cars, motorcycles, agriculture and construction vehicles and industrial trucks), as these products are used for long periods of time and over long distances and require regular maintenance and repair. However, a number of requests were also submitted for other complex articles (such as Electrical and Electronic Equipment).

The respondents indicate that a derogation for the legacy spare parts should be granted to avoid costly and time-consuming material testing, redesign and re-evaluation of affected products/parts. SEAC also notes that several stakeholders indicated that substitution in legacy spare parts would not be possible due to the unavailability of the original vehicles to do a full system validation, which may be needed for safety purpose.

Regarding these requests SEAC rapporteurs acknowledge the complexity – and possible costs - of substituting a substance in a complex article. However SEAC rapporteurs note that the comments do not include information on:

1. what elements of the spare parts contain the substances targeted by this restriction and
2. why substitution would result in a change of design of the spare parts, or their technical characteristics, that would be significant enough to render it unusable.

As there is no sufficient information on the affected components, it is also unclear to SEAC what types of tests would be required and whether the testing of the whole system (e.g. vehicles) would be necessary as part of the substitution activities. For example, SEAC rapporteurs’ understanding is that not for all parts a re-validation has to be based on the original vehicles (while this could be relevant for the safety relevant parts). Therefore from the submitted comments it is unclear whether a component type of approval or an approval on the original vehicle would be needed.

Overall SEAC does not have sufficient information to conclude that the production of legacy spare parts will not be possible as a result of this specific restriction.

SEAC rapporteurs also note that some of the stakeholders made reference to the end-of life vehicles legislations, according to which that spare parts need to be made available for the repair of the vehicles. However, SEAC rapporteurs understanding is that the spare parts do not necessarily need to be produced in the exact same way and composition as the original parts of the vehicle.

SEAC notes that derogations for spare parts could make sense from a circular economy perspective, as these would allow for the repair and maintenance and likely extend the lifetime of affected articles already on the market. However, as highlighted above SEAC’s rapporteurs view is that there is no sufficient evidence demonstrating that the repair and maintenance of articles already placed on the market will no longer be possible because of this specific restriction.

Finally in SEAC’s view, the requested non-time limited character of any such derogations cannot be justified as the affected products would reach their end-of-life also at one point in time. SEAC rapporteurs also note the obligation to provide Legacy Spare Parts is according to national legislations is time limited (e.g. 15 years as mentioned in some comments). Moreover, SEAC’s understanding is that some electronic devices and electrical equipment have a short lifespan.

Overall SEAC considers that the additional information provided in the consultation on the SEAC opinion is not sufficient to justify the need for a derogation for legacy spare parts.

**SEAC rapporteurs’ response to comments regarding the transition period for electrical and electronic equipment (EEE)**

Several respondents requested a longer transitional period for Electrical and Electronic Equipment (EEE) (e.g. for medical device applications and test & measurement instruments, RoHS category 8 and 9 respectively). These requests were mainly based on the argumentation for a longer service life of the equipment, the need of high-quality material and especially PVC cable. Also, according to several respondents emissions from EEE are low because the substances are predominately encapsulated within the equipment.

SEAC rapporteurs consider that the additional information is insufficient to justify the need for a longer transition period considering that none of the producers of materials and/or elements being part of the EEE components (such as rubber producers or producers of cables) requested an extended transition period. Moreover, as documented in the Background Document, the information collected by the Dossier Submitter indicates that alternatives are available in rubber and PVC applications.

Therefore, SEAC agrees with the Dossier Submitter’s conclusion that without more detailed and specific information on the uses and requirements where the substitution is more complex, SEAC has no grounds to justify a longer transition period for this sector.

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| Ref. | Date/Type/Org. | Comments |
| 1221 | Date/Time:  2023/07/07 08:40  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Japan Auto Parts Industries Association(JAPIA)  Org. country:  Japan | General Comments:  JAPIA has been actively promoting activities to comply with the regulations related to chemical substances in each country where our products are used globally, and has implemented effective measures to meet the requirements after its enforcement for the regulations such as REACH. At this time, we support your intention to limit the discharge of MCCP into the environment in order to minimize the impact on people, the environment, etc. We sincerely respect these efforts to reduce future risks. However, we believe that some amendments are necessary to this proposed regulation, which are described below.  1. Transition period for MCCP-containing MWFs needs 15 years We, JAPIA, conducted a comparative test between MCCP and the alternative substances described in the proposed regulations. As a result, it proved that the performance of the alternative substance was insufficient, and even presented a 15-year transition period and its breakdown, but concluded that "the evidence is insufficient." Please show me what else I need to show as proof.  2. Permanent exemption for spare parts A long-term stock of supply parts (spare parts) for vehicle maintenance and repair is essential. With the concept of the circular economy gaining momentum, it is not advisable to dispose of the vehicle in the short term. This restriction not only hampers maintenance and repair of the vehicle, but also shortens the useful life of the vehicle when many spare parts containing MCCP are unavailable. We request an indefinite "exemption" because the longevity of replacement parts is essential for the safe long-term use of automobiles by consumers.  3. Definition of automotive Since automotive is not defined precisely, please add the following description. Defined as :( automotive covering all land-based vehicles, such as cars, motorcycles, agriculture and construction vehicles and industrial trucks).  4. Regarding relaxation of MCCP content in LCCP MCCP content in the only alternative LCCP should be relaxed from 0.1% to 1%. As stated in the proposed regulation, LCCP is the only alternative to MCCP. In addition, MCCP, which is the scope of this regulation, refers to chlorinated paraffins in the range of C14 to C17, and LCCP refers to chlorinated paraffins in the range of C18 and above. Chlorinated paraffins are produced by preparing a broad range of hydrocarbons and chlorinating them. For this reason, it becomes a product with a wide carbon number range to some extent. P20 of the draft regulation states, "The permissible amount of MCCP in LCCP should be 0.1% or less. To achieve this, C20 or higher should be used." This means intentionally excluding C18 and C19. become. This goes against the perspective of the circular economy promoted by the EU as the flagship. Furthermore, when SCCP was regulated by the Stockholm Convention in the past, SCCP in MCCP, the only substitute substance, was permitted up to 1% content. This is an agreement between countries that are parties to the Stockholm Convention, including the EU. In the unlikely event that the Stockholm Convention, which is currently considering the regulation of MCCP, permits the content of MCCP in LCCP to be 1%, there will be a difference from regulations within the EU region. There is concern that this will reduce the competitiveness of the automobile industry within the EU.  5. Exemplary list of regulated substances and their concentrations P3 article 5 states that an example list of regulated substances should be provided, but an exhaustive list should be provided, not an example list. Also, P3 article 6 states that it must be shown that the concentration is below the upper limit, but I would like you to clarify how the analysis should be done in the absence of an exhaustive list of regulated substances.  6. Difficulties in obtaining reference materials Chemical formulas of regulated substances are shown on P5, but reference materials for all chemical formulas do not currently exist. Analysis may be required for compliance with laws and regulations, but currently it is not possible. Based on the above, ECHA is responsible for showing examples of reference materials for all regulated substances. |
| Specific information 1:  We appreciate the longer transition period for metal working fluids than for other applications. JAPIA provides the following four pieces of information. 1. Comparative test results of MCCP-containing processing oils and other alternatives 2. Explanation video of comparison test 3. List of automotive parts that require MCCP-containing processing oil 4. Breakdown of the 15-year transition period requested by JAPIA based on comparative studies If you think that the 4 pieces of information are insufficient, could you tell us what other information JAPIA needs to submit to understand the need for a 15-year transition period? |
| Specific information 2:  According to JAPIA's survey results for automobile parts, processing fluids containing MCCP are defined as "oil-based metalworking fluids" in DIN51385. Therefore, we do not believe that a transition period longer than two years is necessary for other categories of metalworking fluids. |
| Specific information 3:  The SEAC final draft includes the following statement: “The companies in the EU who need these metalworking oils are all small and medium-sized enterprises.In addition, the amount of MCCP used in metalworking fluids is only 5% of the total. Companies that cannot replace the EU should move out of the EU.” If this description is true, I think it will be possible to relocate the factory in seven years. The tangible impact is the economic loss of jobs for these small businesses and the loss of the metalworking industry. Potential impacts include: 1. Since the metal processing industry and the material industry are closely affected, some of the materials industry within the EU will either move to the outside of the EU or lose its trade area. This would impair the optimality of the supply chain and could lead to a deterioration in the competitiveness of automakers in the EU. 2. Metal processing has been and will continue to be a key technology for the automobile industry, and the EU economy, which loses the entire industry, will lose some of its competitiveness. |
|  |  | SEAC Rapporteurs response:  Thank you for your comments and answers to SEAC questions.  SEAC rapporteurs acknowledge that the substitution of substances containing CA:C14-C17 appears to be challenging in metal working fluids, as documented by the stakeholders that participated in the consultation on the Annex XV report and the SEAC Draft Opinion.  Having assessed the additional information submitted by parties in the consultation on the SEAC Draft Opinion, the restriction entry has been amended in the final SEAC opinion to propose a 10-year transition period for this use.  SEAC rapporteurs do not consider that an exhaustive list of substances should be provided, as the restriction is targeting ‘CA:C14-17 with PBT and/or vPVB properties’. So, any substance currently produced (or planned to be produced in the future) is covered by the scope of the restriction, if it contains ‘CA:C14-17 with PBT and/or vPVB properties’ in a concentration above 0.1%. Therefore SEAC rapporteurs support the Dossier Submitter’s dynamic approach, targeting substances with PBT and/or vPvB properties being produced today or in the future.  Thank you for your response regarding DIN 51385.  Finally, regarding specific information 3, please note that the SEAC opinion does not prescribe that companies should relocate outside the EU. The Background Document (and so the SEAC opinion) specify that in case a company is affected by this restriction proposal, one of the possible industry responses in the restriction scenario is the relocation.  Thank you also for providing qualitative information on the economic implications of the restriction on the metal working fluid industry and the downstream impacted industries. SEAC rapporteurs take note that impacts on downstream sectors have been also described qualitatively in the Background Document and these are also discussed in the SEAC opinion.  Regarding your request for a derogation for legacy spare parts, please see SEAC rapporteurs’ general response included at the top of this document. |

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| **1223** | **Date/Time:**  2023/07/27 10:15  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Test & Measurement Coalition  **Org. country:**  Belgium  **Attachment:** | **General Comments:**  On the basis of the strong evidence-based findings reported in the Test & Measurement Coalition’s contribution to the third-party public consultation (i.e., the Socio-Economic Analysis - Analysis of Alternatives report) and the attached critical analysis of SEAC’s opinion, the analysis reasonably justifies a longer transition period of at least 12 years for test and measurement equipment products.  If shorter periods are granted for test and measurement equipment products, the EEA industry will be unable to supply the European markets until the supply chain starts marketing MCCP-free components and T&M producers have completed the transition activities to retain products on the EEA market. This will lead to a shortage in the European markets. |
| **Specific information 1:**  We don’t have specific information on extreme pressure metalworking fluid applications. Nevertheless, we could not help but notice that this is the only longer transition period recommended by ECHA committees. This is despite the large amount of data collected by the TMC in the context of a survey covering >70% of the market for test and measurement equipment. The results of this analysis, which have been presented as part of the input that the Test & Measurement Coalition has provided during the third-party public consultation on the proposed restriction, have not been taken into account by SEAC in the opinion development. These evidence-based findings support a longer transition period of at least 12 years for test and measurement equipment products. |
|  | SEAC Rapporteurs response:  Thank you for your comments and answers to SEAC questions.  In your submission you indicate that the T&M coalition’s contribution to the public consultation on Annex XV (comment # 3826) has not been considered by SEAC rapporteurs in the final opinion. Please note that the submitted comment as well as the submitted Socio-Economic Analysis (SEA) were assessed by SEAC rapporteurs. However, SEAC rapporteurs consider that no sufficient information is available to conclude that a transition period of 12-years should be recommended for test and measurement equipment (Category 9 under Annex I of RoHS).  SEAC would like to stress that - in the consultation on the SEAC draft opinion - no company producing cables requested a derogation or a transition period longer than 2 years. SEAC rapporteurs’ understanding is that the companies producing cables will be able to transition to the relevant alternatives within two years from the entrance into force of the restriction. Also SEAC did not receive in the consultation on the draft opinion any information that the suppliers of cables will have to cease their production and sales because of the inability to transition to an alternative. Therefore, it is unclear to SEAC why the production of test and measurements equipment – the production of which is relying among other things on the supplies of cables - would be impacted in the restriction scenario with a transition period of 2 years.  SEAC would like also to stress that the information the Dossier Submitter collected in the preparation of the dossier did not show the need for a longer transition period for reformulating and testing the compounds to produce cables. Dossier Submitter also collected information from the European association (PVC4cables) and no request for a longer transition period was submitted by this organisation either (Section 2.2.2.1 of the Background Document).  Considering the above considerations, SEAC does not have sufficient and consistent evidence to conclude that the T&M industry’s response to the restriction conditions, as presented in the submitted Socio-Economic Analysis (comment # 3826 on the Annex XV report), is the most likely one. Therefore, SEAC rapporteurs consider that there are major uncertainties on whether the described economic impacts (e.g. in terms of profit losses and social impacts) will materialise as a result of the restriction. |

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| **1224** | **Date/Time:**  2023/07/28 16:50  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Germany Association of the Automotive Industry  **Org. country:**  Germany  **Attachment:** | **General Comments:**  The automotive industry has been actively promoting activities to comply with the regulations related to chemical substances in European union and globally, and has implemented effective measures to meet the requirements after its enforcement for this regulation. At this time, we support your intention to limit the discharge of MCCP into the environment in order to minimize the impact on people, the environment, etc. We sincerely respect these efforts to reduce future risks. However, we believe that some amendments are necessary to this proposed regulation, which are described in the attachment. |
| **Specific information 1:**  We appreciate the longer transition period for metal working fluids than for other applications. We added some information in the attached document. |
| **Specific information 3:**  The SEAC final draft recognizes the need to extend the use of metal working fluids, which we highly appreciated. A total ban would lead to the economic loss of jobs for these small businesses and the loss of the metalworking industry. Following potential impacts include must be considered: 1. Since the metal processing industry and the material industry are closely affected, some of the materials industry within the EU will either move to the outside of the EU or lose its trade area. This would impair the optimality of the supply chain and could lead to a deterioration in the competitiveness of automakers in the EU - especially after the insight gained from the situation with Covid-19 and the Ukraine war - that heavy dependence on imports should be avoided, 2. Metal processing has been and will continue to be a key technology for the automobile industry, and the EU economy, which loses the entire industry, will lose some of its competitiveness. Further details are described in the attachment. |
| SEAC Rapporteurs response:  Thank you for your comments on the SEAC Draft Opinion, which complement the submission of comments on the Annex XV report (comment #3839).  1. SEAC rapporteurs acknowledge that the substitution in metal working fluids appears to be challenging on technical and economic grounds, as documented by the stakeholders that participated in the consultation on the Annex XV report and on the SEAC Draft Opinion. Having assessed the additional information submitted by parties in the consultation on the Draft Opinion, the opinion has been amended to propose a 10-year transition period for this use.  2. With regard to the request for a transition period of 5 years, SEAC does not consider that the provided evidence is sufficient to justify its need.  Page 2 of the submission provides some generic information on the substitution steps required when substituting a substance in a car component. However, the information provided does not:  1. include information on the exact component/s being affected by the restriction  2. provide information on the types of tests required considering the impacted components  3. provide information on how the 5 years were determined  4 explain whether all the phases reported on page 2 (such as vehicles testing) would be required considering the affected components.  Also SEAC did not receive any information from the materials suppliers and suppliers of more “simple” articles that a longer transition period is needed.  With regard to the request for a permanent derogation for Legacy Spare Parts, SEAC rapporteurs have the following observations:  1. No information has been provided on what elements of the spare parts contain the restricted substances. In your comment you indicate that the quantity of the substance EC 287-477-0 used in legacy spare parts will range from 1.29 kg to 46.5 kg in 2026, dwindling to 0.06 to 2.3 kg in 2041. However, no information is provided on what elements of the Legacy Spare Parts are affected.  2. As there is no information on the affected components, it is also unclear what types of tests would be required and so it is unclear to SEAC whether the whole vehicles testing would be needed as part of the substitution activities.  For example, SEAC rapporteurs’ understanding is that not for all parts a re-validation has to be based on the original vehicles (while this could be relevant for the safety relevant parts). Therefore from the submission it is unclear whether for the specific parts affected by this restriction a component type of approval or an approval on the original vehicle would be needed.  3. Finally SEAC rapporteurs consider that the non-limited time of such a derogation cannot be justified as the obligation to provide Legacy Spare Parts is limited according to national legislations is time limited (e.g. 15 years as mentioned in your comment).  Please see also the general response included at the top of the document.  Based on the above considerations SEAC concluded that no sufficient information is available to justify a derogation for legacy spare parts and so no changes in the opinion have been included in this regard. |

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| **1225** | **Date/Time:**  2023/07/31 04:39  **Type:**  BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Japan Electronics and Information Technology Industries Association (JEITA)  **Org. country:**  Japan | **General Comments:**  We, Japanese electric and electronic industrial associations : JEITA (Japan Electronics and Information Technology Industries Association); CIAJ (Communications and Information Network Association of Japan); JBMIA (Japan Business Machine and Information System Industries Association); and JEMA (Japan Electrical Manufacturers’ Association) have been vigorously committed to improving environment and to complying with chemical regulations set by EU and other countries including the U.S. and China, etc. We have submitted our input twice for the dossier on MCCP and this is the following -up of our previous input. Japan 4EE basically support the recommendations in the RAC/ SEAC Opinion on an Annex XV dossier proposing restrictions on MCCP and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17. We thank ECHA very much for having taken the industry’s opinion into consideration.  (1) Current recommendation set a general transitory period as 24 months. We can basically support the proposal, however, our products, electrical and electronic equipment, hereinafter “EEE”, need at least 48 months as transitory period before the restriction of substances contained in the complicated articles. In addition, even if MCCP is covered under the EU POPs Regulation in future, the general transitory period should be kept as considered under REACH. We feel concern about PFHxS case, where 18 months’ transitory period was proposed under REACH but no period is given under POPs regulation. Justification: EEE is made at the end of the global long and winding supply-chain, and the chemicals in concern are used at upstream in many cases. Current listing of MCCP on the Declarable Substance List under IEC 62474 is based on the Candidate List of Substances of Very High Concern, SVHC, and the EEE industry has not been able to complete the investigation on the additional substances covered under the broader scope of the proposed restriction. As the current opinion seems to cover broader scope of substances than those covered under the dossier, the industry also would need longer time to cope with the restriction than that required in our previous input. Even if ECHA publishes an indicative list of identifiers describing substances that may contain MCCP within three months after entry into force of the restriction, about 20 months would be too short for the complex article manufacturers to investigate and substitute such many substances in products. Also, the time required for substitution of substances does not change, whether the applicable regulation is the REACH Regulation or the POPs Regulation.  (2) About metal working fluids, we support the recommendation which proposes a general seven years’ derogation for all the extreme pressure metal working fluid as defined under DIN 51385. Seven years must be tight for EEE, but we would try to comply with the timeline. However, some kinds of EEE, for example, those used for medical practice (such as clinical, diagnostic, inspection, analysis, monitoring and others) and industrial and other types of monitoring, control, analysis and measurement equipment, in laboratories, infrastructure of transportation, lifelines, security, disaster preventions, and process control of many types of production and so on, may need longer derogation. Please refer to the input from the relevant industries.  (3) Availability of spare part must be secured to establish circular economy. We believe that derogation for spare parts for old products should be set. A General exemption of spare parts without expiry date would be indispensable for complex articles to extend their useful life, if their original products are placed on EU market before the requirement comes into force. Justification: The change of important parts, including the change of their materials, is never a simple task. Even if some alternatives are proposed by chemical manufacturers in future, there is no guarantee that the same performance as before can be obtained. The device manufacturers such as semiconductor industry must assess their performance, reliability, safety or any other features of such alternatives. Furthermore, the change of the very important parts often needs redesign of the finished products as a whole. Such redesign is beyond "repair" process.  We would very much appreciate it if ECHA would kindly consider our input further.  About Japanese electric and electronic (E&E) industrial associations: About JEITA: The objective of the Japan Electronics and Information Technology Industries Association (JEITA) is to promote the healthy manufacturing, international trade and consumption of electronics products and components in order to contribute to the overall development of the electronics and information technology (IT) industries, and thereby further Japan's economic development and cultural prosperity.  About CIAJ: Mission of Communications and Information network Association of Japan (CIAJ). With the cooperation of member companies, CIAJ is committed to the healthy development of info-communication network industries through the promotion of info-communication technologies (ICT), and contributes to the realization of more enriched lives in Japan as well as the global community by supporting widespread and advanced uses of information in socio-economic and cultural activities.  About JBMIA: Japan Business Machine and Information System Industries Association (JBMIA) is the industry organization which aims to contribute the development of the Japanese economy and the improvement of the office environment through the comprehensive development of the Japanese business machine and information system industries and rationalization thereof.  About JEMA: The Japan Electrical Manufacturers' Association (JEMA) consists of major Japanese companies in the electrical industry including: power & industrial systems, home appliances and related industries. The products handled by JEMA cover a wide spectrum; from boilers and turbines for power generation to home electrical appliances. Membership of 291 companies, http://www.jema-net.or.jp/English/ |
|  |  | SEAC Rapporteurs response:  Thanks for your comments.  SEAC rapporteurs acknowledge that the substitution in metal working fluids appears to be challenging on technical and economic grounds, as documented by the stakeholders that participated in the consultation on the Annex XV report and on the SEAC Draft Opinion. Having assessed the additional information submitted by parties in the consultation on the Draft Opinion, the opinion has been amended to propose a 10-year transition period for this use.  Regarding derogation for legacy spare parts, SEAC does not consider that sufficient information has been provided to justify a derogation. Please see also SEAC’s general response at the top of the document as well as response to comment #1224.  As in response to comment #1224, SEAC’s view is that there is no sufficient information on the impacted spare parts’ components and evidence that the spare parts will not be available as a result of the restriction. However, SEAC rapporteurs’ understanding is that the substitution might be more complex in case the substitution would require the redesign of the finished products.  Regarding your request for a longer transition period, SEAC does not consider that the information submitted is sufficient to justify a longer transition period as no specific information has been provided on why a TP of 2 years would not sufficient.  Also SEAC notes that in consultation on Annex XV dossier comment #3639, 36 months instead of 48 months were mentioned for complex articles such EEEs. |

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| 1226 | Date/Time:  2023/08/01 20:32  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Test & Measurement Coalition  Org. country:  Belgium  Attachment: | General Comments:  On the basis of the strong evidence-based findings reported in the Test & Measurement Coalition’s contribution to the third-party public consultation (i.e., the Socio-Economic Analysis - Analysis of Alternatives report) and the attached critical analysis of SEAC’s opinion, the analysis reasonably justifies a longer transition period of at least 12 years for PVC high performance applications within test and measurement equipment products, given that:  - Approximately 85% of T&M product portfolios would be impacted and would require redesign; - Recognizing the greater difficulty in redesigning test and measurement equipment; - Taking into consideration the high economic and reformulation costs; - Considering the low tonnage of used MCCPs and their very minor release in the environment, if compared to other sectors.  If shorter periods are granted for test and measurement equipment products, the EEA industry will be unable to supply the European markets until the supply chain starts marketing MCCP-free components and T&M producers have completed the transition activities to retain products on the EEA market. This will lead to a shortage in the European markets and a negative impact on the competitiveness of the EEA industry. |
| Specific information 1:  We don’t have specific information on extreme pressure metalworking fluid applications. Nevertheless, we could not help but notice that this is the only longer transition period recommended by ECHA committees. This is despite the large amount of data collected by the TMC in the context of a survey covering >70% of the EEA market for test and measurement equipment. The results of this analysis, which have been presented as part of the input that the Test & Measurement Coalition has provided during the third-party public consultation on the proposed restriction, have not been taken into account by SEAC in the opinion development. These evidence-based findings support a longer transition period of at least 12 years for test and measurement equipment products. |
|  |  | SEAC Rapporteurs response:  Thank you for your comment. See response to comment #1223. |

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| 1227 | Date/Time:  2023/08/04 11:04  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  EuPC (European Plastics Converters)  Org. country:  Belgium  Attachment: | General Comments:  Summary statement Based on robust facts and data, MCCPs can be safely recycled at a level of 4wt% in recyclate. Not to allow this derogation will result in approximately 100,000 tonnes of post-consumer waste cable sheathing to be lost from the circular economy. This will end the recycling of cable sheathing with the waste then being landfilled or incinerated. This will have associated negative economic and environmental impacts of between 191 and 250 million EUR. In view of these facts we call on ECHA SEAC to support a derogation of 4wt% of MCCP in recyclate.  General  The SEAC draft opinion considers not to take into account our previous comment with the following 3 arguments 1) SEAC opinion : Most articles containing recycled PVC cable are intended for outdoor uses which would lead to uncontrolled releases. Comment : We question this assessment. We have quantified those releases as 1,56 Tonnes per year (i.e. 31,2 Tonnes at most in 20 years : this is an absolute maximum since it can be expected that more and more formulation not containing MCCP will be recycled over time : see below). This should be compared to the 100,000 tonnes releases avoided over 20 years according to the dossier submitter. This level of 1,56 Tonnes release per year would correspond to a limit of 4% MCCP content. We are lacking experience on how fast this level could be decreased, but a revision clause in the restriction could ensure a steady concentration decrease is ensured. Releases would remain very low and be proportional to the concentration limit set. 2) SEAC opinion : The recycling activity is mainly driven by metal recovery in the cable sector. Comment : This is correct. However, the fact remains that stopping the recycling of PVC cables sheathing and jacketing would result in a cost for society estimated between 191 and 250 million € per year (see below). 3) SEAC opinion : Difficulty for enforcement. Comment : In our last comment we proposed that the amount of MCCP in recycled applications should be limited to maximum of 4%, a rate at which MCCP would not perform a meaningful function as a flame retardant plasticiser. This combined with a restriction on the end uses would ensure ease of enforcement. For the sake of consistency we referred to the restriction on DEHP, BBP, DiBP and DBP and its derogation (articles exclusively for industrial or agricultural use, or for use exclusively in the open air). More specific applications such as traffic management could be specified.   We would therefore propose the following derogation to be applied for the recycling of recycled compound and articles containing MCCP impurities.  1) Use of recycled PVC compounds containing MCCP shall be limited to articles exclusively for industrial or agricultural use, or for use exclusively in the open air 2) The maximum allowed MCCP content in PVC recycled compound/articles would be 4% (i.e. an additivation rate at which MCCP do not perform their intended function as flame retardant plasticisers in cables) subject to a revision after x years.   Uses  MCCP are still used in a range of PVC cables to impart flame retarding performance today. It may therefore be expected that those MCCP will be found in cables to be recycled in the future. For the specific grades of cables where they are used, MCCP content may reach up to 15%. It is not evident how selection could be made, but grades of cables with lower concentrations of MCCP may be obtained. From past VinylPlus analysis however a level of 0,1% cannot be guaranteed.  The main use of cable based recyclate is in articles for traffic management, industrial applications and agriculture (industrial coils, soft profiles). In 2022, 99,000 tonnes of post-consumer cable were registered in the Recovinyl Recotrace system.  Socio-economic impact  Without any derogation, the restriction as it is proposed will lead to the end of post-consumer cable recycling. A previous report done by RDC Environment in 2018 on the same application shows that benefits from recycling add up to 1818 €/T PVC processed (Economic, job and monetized environmental impact, health)[ (Cost-benefit analysis of recycling PVC applications containing lead, report for VinylPlus, RDC, February 2018, table 12, p. 41 available in Annex 1) . It is estimated that 100,000 tonnes of articles mainly for traffic management were sold in the EU in 2022 (Recovinyl 2022). Alternative waste treatment routes result in a cost of 736 €/T for incineration and 92 €/T for landfill. This materializes into a monetized benefit of recycling vs. incineration of 255 million € and 191 million € vs landfill.   This socio-economic impact could however be avoided without any issue for enforcement by granting a derogation for use in selected applications. We would recommend to align the derogation to the one on DEHP in PVC i.e. allowing only uses in articles exclusively for industrial or agricultural use, or for use exclusively in the open air. The limitation regarding prolonged contact with skin is in this case not relevant as this restriction was introduced to protect human health against reprotoxic properties of DEHP.  The release of MCCP from the PVC matrix is estimated to be limited. If we refer to the release rates in table S5 of a recent study on the Release Mechanism of Short- and Medium-Chain Chlorinated Paraffins from PVC Materials Under Thermal Treatment (Haoran et.al 2023) , releases of MCCP are expected to be around 2,2 10-6/day. Taking into account that not all formulation will contain MCCP and that using the above release rate would result in releases amounting to a maximum of 5,84 tonnes per year in case no limit is set for MCCP content. In case lower concentrations in recycled applications would be allowed, releases would be decreased to 1, 56 Tonnes peryear with a residual content of 4% MCCP. At those levels of additivation, the MCCP do not perform their function anymore (i.e. no virgin formulation exist at such low levels). With a MCCP content of 1%, releases would amount to 389 kg/year for the whole of Europe (for detailed calculations see table in appended comment) .  Those lower MCCP residual contents (4% and 1%) could be considered in combination by a limitation of end application in order to only allow recycling of PVC waste containing the specified residues of MCCP. |
| Specific information 4:  It is difficult to provide a fully accurate estimate to this question, which actually aims at determing if the restriction of Pb in PVC cables would not already lead to a decrease of PVC cable recycling. Residual Pb levels in post consumer PVC cable decrease rapidly. In recent measurements by recyclers, we observe that Pb levels in post consumer PVC cable to be around 0,3% maximum and in recyclate not exceeding 0,2%. New sorting techniques are being developed (X-ray fluorescence, including continuous processes). Combined with careful selection of input material this could therefore lead to reaching the restriction limit by end May 2025. |
|  |  | SEAC Rapporteurs response:  Thank you for your comments and answers to SEAC questions.  In your comment you propose to add a derogation allowing the use of recycled PVC compounds containing CA:C14-17 in articles exclusively for industrial or agricultural use, or for use exclusively in the open air.  SEAC however considers that the arguments provided (and which were already submitted in the consultation on Annex XV report, comments #3848) do not justify the need for a higher concentration limit for recycled PVC for the reasons provided in the ORCOM document and which have been also reflected in the SEAC Draft opinion.  As substances containing CA:C14-17 (in a concentration above 0.1%) are PBT and/or vPvB, and that the objective of the restriction proposal is to decrease their releases to a maximum extent, SEAC rapporteurs consider that your proposal goes into the opposite direction of the restriction’s objectives.  SEAC would like to further stress that most of the articles produced with PVC recyclates are intended for an outdoor use (such as road traffic management and agricultural articles) and pose an uncontrolled risk in terms of emissions of EC 287-477-0 and other substances containing ‘CA:C14-C17 with PBT and/or vPvB properties’.  Finally, regarding the limit concentration (point 3 of your comment), SEAC notes that some producers of PVC cables indicated 4% as the lower bound for the concentration of EC 287-477-0 in certain cables.  Overall SEAC rapporteurs’ do not consider that there is a need to modify the opinion based on your comments. |

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| 1228 | Date/Time:  2023/08/08 11:55  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes  Attachment:  <redacted>  Privacy statement:  Protection of our commercial interests, including intellectual property | General Comments:  All comments can be found under specific information requests and our confidential attachment. |
| Specific information 1:  To proof that we need a longer transition period than 7 years we did some trials with MCCP-based compared to MCCP-free deep drawing lubricants. As already mentioned in comment on Annex XV, during the forming process enormous temperatures and pressures occur for a very short time in the forming zone between the drawing ring and the sheet metal, which cannot be measured due to the high dynamics of the process at the effective point in the drawing gap. However, the effects can sometimes be observed as the formation of oil carbon on the workpieces and tools. If the lubrication fails under these enormous loads, micro-welding immediately occurs between the stainless-steel sheet and the drawing ring. This immediately leads to scoring on the stainless-steel sleeves - drawn from the sheet - and thus to process failure. In the literature, the excellent lubricating properties of chlorinated paraffins are attributed, among other things, to the formation of metal chloride or iron chloride during forming. The iron chloride serves as a sliding/separating layer between the tool and the material. This is what we want to show with the trial you can find attached to this comment as a confidential attachment. |
| Specific information 3:  A ban on manufacturing of MCCP containing metalworking fluids would cause a production stop of all coplex article groups that need MCCP for deep drawing process like stainless steel, nickel alloys (and alloy) and titanium. We have occasionally succeeded in replacing MCCP oils with LCCP oils for some articles. So far, these are individual cases with simpler tribological requirements (lower surface pressure, lower drawing length and speed). In many cases, LCCP oils cannot meet the tribological requirements for stainless steel that can be achieved with MCCP oils. This is also true when using the best available carbide tools with hard coatings and lubrication pockets. A ban on the production and marketing of substances, mixtures and articles containing more than 0.1% CA:C14-17 with PBT and/or vPvB properties may also result in no LCCPs with C18-... being available, as oil producers will not be able to meet this requirement. However, if no chlorinated paraffines are available at all, a timeframe for conversion cannot be planned and thus cannot be predicted. For this reason, we request an exemption to continue using MCCP for the process: "Deep drawing of stainless steels, alloy and titanium with a high degree of deformation/drawing ratio for complex parts/moulds". With a ban on the use of substances containing more than 0.1% MCCP and without an adequate substitute there is a high risk that 282 articles with a sales volume of € 56.3 € million cannot be converted per year. Loss of turnover in the amount of approx. 56.3 million euros. This equals 39,4% of the annual turnover. As a result, the personnel expenses would need to be consequently adjusted accordingly. This would lead to the layoff of ~ 331 employees. High probability of relocations to production sites in North America and Asia. Approximately 1,15 billion parts will not be produced in the future. Summary: Dramatic staff reductions, relocation of production to non-European countries. |
|  |  | SEAC Rapporteurs response:  Thank you for your comments, answers to SEAC questions and for providing confidential information on the tested alternatives.  SEAC rapporteurs acknowledge that the substitution in metal working fluids appears to be challenging on technical and economic grounds, as documented by the stakeholders that participated in the consultation on the Annex XV report and on the SEAC Draft Opinion. Having assessed the additional information submitted by parties in the consultation on the Draft Opinion, the opinion has been amended to propose a 10-year transition period for this use.  SEAC also notes that long chain chlorinated paraffins (EC 264-150-0) with C18 is only one among the potential alternatives. So the relevant sectors can already factor the information that this specific alternative (which might be technically feasible for certain types of fluids) may not be available once the restriction enters into force and so focus the substitution efforts on other potential alternative formulations. |

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| 1229 | Date/Time:  2023/08/09 15:26  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  EUROMOT - The European Association of Internal Combustion Engine and Alternative Powertrain Manufact  Org. country:  Belgium  Attachment: | General Comments:  EUROMOT, the European Association of Internal Combustion Engine and Alternative Powertrain Manufacturers, represents the key manufacturers of internal combustion engines and alternative powertrains installed in industrial non-road mobile machinery, marine and stationary applications that are operating in Europe and worldwide. EUROMOT member products are extremely complex, internal combustion engines typically have between 1200 to over 2000 components and electric engines have more than 200 parts. The scale of the number of components gives an insight into the high complexity of these devices. Moreover, EUROMOT members’ products are highly integrated complete systems for power supply. These need to be adapted to the respective application or end use to fulfil the required work task, for example the quality of the operating fuels and the operating conditions (temperature, humidity, harsh chemical environment). EUROMOT members’ engines must comply with EU emissions legislation and so are designed with an array of electrical controls with sensors and actuators to maximise performance with minimum emissions. Any changes to these designs must be approved by an EU Notified Body before the modified engine can be used in the EU. EUROMOT members support the goal of reducing emissions of MCCPs of concern in the environment. However, considering the long development times of EUROMOT members’ products, a too short transition time for a ban on this group of substances would have far-reaching consequences for our industry. Therefore, EUROMOT proposes some changes to the proposed restriction. After reviewing the ECHA’s restriction proposal for a restriction of Medium-Chain Chlorinated Paraffins (MCCP) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17, EUROMOT would like to recommend the following change to the current proposal: Exemption required for legacy spare parts, and remanufactured parts, affecting the proper functioning related to the safety and reliability of Internal Combustion Engine systems and affecting the safety of humans or reliability of equipment. For more details please see attachment. |
| Specific information 1:  For more details please see attachment. |
| Specific information 2:  For more details please see attachment. |
| Specific information 3:  For more details please see attachment. |
| Specific information 4:  For more details please see attachment. |
|  |  | SEAC Rapporteurs response:  Thank you for your comment.  Regarding the request for a derogation for legacy spare parts, please see the general response at the top of the document as well the response to comment #1224. Also, from your submission it is not clear what components are affected and whether the whole systems would need to be redesigned to permit the use of the component manufactured with the alternative.  Moreover, the permanent character of the derogation request is not justified in SEAC rapporteurs’ view, also considering that in your submission it is indicated EUROMOT members’ products have a lifespan of 20-25 years. |

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| 1230 | Date/Time:  2023/08/10 10:18  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Japan Electric Measuring Instruments Manufacturers’ Association  Org. country:  Japan | General Comments:  We, electric equipment manufacturers’ coalition of medical devices, and analysis, measurement, test, control and monitoring instruments in Japan (here-in-after “Japan Category 8 & 9”), are: JAIMA (The Japan Analytical Instruments Manufacturers’ Association); JEMIMA (Japan Electric Measuring Instruments Manufacturers’ Association); JIMA (The Japan Inspection Instruments Manufacturers’ Association); JMIF (Japan Measuring Instruments Federation); NECA (Nippon Electric Control Equipment Industries Association), SEAJ (Semiconductor Equipment Association of Japan) and IGMA (Industrial Gas Detectors and Monitors Manufacturers Association).  If the derogations below are considered, efficient and feasible fades out of MCCPs will be achieved: - The spare (repair) parts which are used for EEE used for social infrastructure placing on the EU market before the entry into force should be derogated from the restriction - MCCPs in articles of PVC and rubbers in EEE used for social infrastructure should be derogated from the restriction for long years.  We manufacture electrical and electronic equipment used for social infrastructures, such as, medical practice (such as clinical, diagnostic, inspection, analysis, monitoring and others) and industrial and other types of monitoring, control, analysis and measurement equipment, in laboratories, infrastructures of transportation, lifelines, security, disaster preventions, and process control of many types of productions (here in after collectively called “EEE used for social infrastructure” in this comment). The EEE used for social infrastructure are made in small numbers, are produced for long periods without modification or changes, have to be reliable and need long term test for reliability. The instruments would have been replaced typically after 7-10 years or more from the release of the products. The supply chains are very long and take time to eliminated restricted substances from the supply chain. Table 5-4 Amount of EEE (tons) put on the EU market, per year and product category, “Support for the Evaluation of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Final Report” shows the percentage of category 8 and 9 products is only 3.5 of all amount of electric and electronic equipment(EEE) (tons) put on the EU market. Spare (repair) parts should be derogated. Most EEE used for social infrastructure is in the scope of EU RoHS Directive. The spare (repair) parts which are used for EEE placing on the EU market before the entry into force are derogated from the EU RoHS Directive according to Article 4. The number of the item in the instrument is small; however, the instruments have a wide variety of models. These are often customized for each customer. If the instruments cannot have repair parts as produced, the instruments will not be able to be repaired, and then it might shorten its lifetime and abandoned earlier than its intended lifetime which are often 10 years or more. Spare (repair) parts for EEE used for social infrastructure are manufactured during the production of the products and spare parts. The number of the spare parts are estimated for all their lifetime. When the production of the products is finished, the production of their spare parts is finished. Engineering design change is impossible because their products is not available anymore. Therefore, the derogation for spare(repair) parts are allowed with EU RoHS Directive. We hope the derogation for spare(repair) parts in REACH Regulation Longer grace period should be considered. . Particular attention needs to be paid to the fact that PVC cable standards are cited in the safety standards of IEC 61010-1, IEC 60799, which refer to IEC 60227: Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V. Some of these LVD harmonised standards limit the use of rubber or PVC only, and in such cases a large number of devices actually use PVC cables in accordance with IEC 60227. IEC 60601-1 cites IEC 60227: Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V IEC 61010-1 and IEC 60601-1 are required with EEE used for social infrastructure. If the electric and electronic equipment mentioned above cannot use MCCPs in PVC anymore and MCCPs in PVC are to be substituted, the long grace period is required in order to test the product to comply with the safety requirements defined with IEC standards, and obtain the re-certificates according to the requirements. The engineering design changes take long period.  EEE uses parts manufactured with metalworking fluids containing MCCPs as an extreme pressure additive. The duration for 7 years in the Draft opinion is still challenging, however, we support for the duration. LCCPs is required for the metal working fluid. |
|  |  | SEAC Rapporteurs response:  Thank you for your comment.  Regarding the derogation for spare parts, please see the response included at the top of the document as well as response to comment #1224. Also, from your submission it is not clear what components are affected and whether the whole systems would need to be redesigned to permit the use of the component manufactured with the alternative.  SEAC rapporteurs acknowledge that the substitution in metal working fluids appears to be challenging on technical and economic grounds, as documented by the stakeholders that participated in the consultation on the Annex XV report and on the SEAC Draft Opinion. Having assessed the additional information submitted by parties in the consultation on the Draft Opinion, the opinion has been amended to propose a 10-year transition period for this use. |

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| 1231 | Date/Time:  2023/08/10 12:23  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Verband Schmierstoff-Industrie e.V.  Org. country:  Germany | General Comments:  siehe unten stehende Kommentare |
| Specific information 1:  Schwierige Umformoperationen benötigen nach wie vor MCCP als Leistungsadditiv. Aufgrund hoher Entsorgungskosten wird schon heute, wo immer möglich, auf MCCP verzichtet. Man kann davon ausgehen, das es in Fällen, wo es immer noch eingesetzt wird keinen Ersatz gibt. |
| Specific information 2:  Eine Schlüsselandwendung für MCCP in Metallbearbearbeitung ist Feinschneiden und Stanzen. Diese Anwendungen sind nicht in der DIN 51385 beschrieben. Nach dem Stand der Technik gibt es hier bislang keinen Ersatz für MCCP, zumindest bei bestimmten Materialien (Edelstahl, Titan etc.). Daher sollten die Anwendungen mindestens wörtlich in der Ausnahme genannt werden. |
| Specific information 3:  Eine Beschränkung von MCCP in Metallbearbeitungsflüssigkeiten würde nach heutigem Stand zu einer Verlagerung der Produktion führen, da die mittels MCCP außerhalb der EU gefertigen Bauteile keiner Beschränkung unterliegen würden. |
|  |  | SEAC Rapporteurs response:  Thank you for your comment and specifying which metal working operations are not covered by DIN 51385.  To ensure that all the relevant Metal Working Fluids (MWFs) are covered, the restriction entry as proposed by SEAC in the final opinion has been amended to remove the reference to DIN 51385. |

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| 1232 | Date/Time:  2023/08/10 13:20  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  European Automobile Manufacturers' Association (ACEA)  Org. country:  Belgium  Attachment: | General Comments:  The automotive industry has been actively promoting activities to comply with the regulations related to chemical substances in the European Union and globally, and has implemented effective measures to meet their requirements after entry into force.  The industry supports the intention to limit the discharge of MCCP into the environment in order to minimize the impact on human health and the environment, as these efforts are needed to reduce future risks.  However, we believe the current wording of the proposed restriction might have a disproportional effects on vehicle production, and that some amendments are necessary to this proposed regulation, which you will find described in the attached annex. |
| Specific information 1:  We appreciate the longer transition period for metal working fluids than for other applications. Please find some additional information in our attachment. |
| Specific information 3:  The SEAC final draft recognizes the need to extend the use of metal working fluids, which we highly appreciated. A total ban would lead to the economic loss of jobs for these small businesses and the loss of the metalworking industry. The following potential impacts include must be considered: 1. Since the metal processing industry and the material industry are closely affected, some of the materials industry within the EU will either move to the outside of the EU or lose its trade area. This would impair the optimality of the supply chain and could lead to a deterioration in the competitiveness of automakers in the EU - especially after the insight gained from the situation with Covid-19 and the Ukraine war - that heavy dependence on imports should be avoided. 2. Metal processing has been and will continue to be a key technology for the automobile industry and therefore for the competitiveness of the EU economy. Further details are described in the attachment. |
|  |  | SEAC Rapporteurs response:  Thank you for your comment and answers to SEAC questions.  As the content of your submission is the same as the comment submitted by the Germany Association of the Automotive Industry, please see SEAC rapporteurs’ response to comment #1224. |

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| 1233 | Date/Time:  2023/08/11 10:33  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Japan Business Council in Europe (JBCE)  Org. country:  Belgium  Attachment: | General Comments:  JBCE understands that the proposed restriction proposal for MCCPs is in line with the target of having “a zero-pollution ambition for a toxic-free environment” which was proposed in the “Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment- (CSS)”. However, despite agreeing with and supporting its concept and purpose to protect human health and the environment, we would like to point out that the currently proposed restriction raises various issues which need to be addressed in terms of scientific reasoning and socio-economic impact, as highlighted by various companies across different impacted sectors represented by JBCE. Our main points of concern are listed below.  1: Sufficient transition period for the final products 1-1: Investigation of MCCPs contained in the final products through long supply chains • Regarding the conditions of restriction, point 5 states, regarding identifiers of covered substances, that “[Within three months after entry into force] of the restriction, the European Chemicals Agency shall publish and maintain on its website an indicative list of identifiers describing substances that may contain the chloroalkanes listed in column 1]”. MCCP is a Substance of very high concern (SVHC), but the proposal is broader than the current scope of MCCP as SVHC. • To correctly investigate the MCCPs contained in the products, not only the description based on the chemical composition but also specific identifiers such as EC numbers and/or CAS numbers are essential. It will only be after the release of the list that the upstream companies can investigate the presence and overall concentration of MCCPs in the products and inform their downstream users and customers. Since the supply chain is long and international, final product manufacturers need sufficient time to collect the information from their suppliers.  1-2: Sufficient time to check the performance of final products • After an alternative substance to MCCPs is found, it still needs to be proven whether final products show the same level of performance, safety, durability and robustness after design changes or not. A special derogation is necessary for some products - such as medical devices - which need to go through certification processes again after the introduction of new substance restrictions. This work requires financial and above all human resources. A shortage of specialist causes a delay in R&D activities.  1-3: Long transition period for specialist devices • Especially for specialist devices such as medical devices, in vitro diagnostic medical devices as well as monitoring and control devices, a longer transition period is necessary. These devices have longer lifespans and longer design cycles than B2C electrical and electronic equipment (EEE) and, consequently, they need a longer transition period. In fact, it is for this reason that the RoHS Directive gives longer transition periods for these devices compared to other B2C EEE. These devices contribute to society through, for example, diagnostics (e.g. PCR tests), measuring hazardous chemicals, environmental monitoring (e.g. air pollution, water quality), safety monitoring (e.g. fire warning, product safety) and innovation (e.g. development of new pharmaceutical products). If the transition period is too short, these devices cannot be placed on the EU market and consequently it will negatively impact society.  For the above reasons, JBCE asks for a sufficiently long transition period to be set after the list of identifiers is published to avoid socio-economic disruption. The two-year grace period proposed by SEAC is too short for the industry to implement the requirements. Sector-specific sufficient transition periods should be introduced.  2: Spare parts: A “repair as produced” principle should be introduced • JBCE strongly believes that spare parts for EEE placed on the market before the implementation of the restriction should be excluded from the restriction without an expiry date. If spare parts are not exempted, the lifetime of EEE will be shortened. Consequently, the volume of waste of EEE will rapidly increase, which is undesirable from the viewpoint of circular economy. Therefore, a “repair as produced” principle should also be introduced as it is the case in the RoHS Directive (2011/65/EU). • Furthermore, we believe that these measures are needed not only for EEE but also for motor vehicles, industrial machines for use in agriculture and construction, marine, garden and outdoor power equipment, including forestry machinery, aerospace and defence applications, medical imaging and radiotherapy devices. Appropriate consideration needs to be given to each of these applications. • In addition, reuse of used parts/used equipment should be exempted from the restriction without expiry date in order to make the EU society more sustainable. |
|  |  | SEAC Rapporteurs response:  Thank you for your comments and answers to SEAC questions.  On the first point of your comment, SEAC rapporteurs do not consider that an exhaustive list of substances should be provided, as the restriction is targeting ‘CA:C14-17 with PBT and/or vPVB properties’. So, any substance currently produced (or planned to be produced in the future) is covered by the scope of the restriction if it contains ‘CA:C14-17 with PBT and/or vPVB properties’ in a concentration above 0.1% . When testing a mixture or an article, the analytical capability allows the identification of congeners but cannot attribute the congeners to a specific CAS/EC number. Therefore, SEAC rapporteurs do not consider that an exhaustive list of substance with EC/CAS number will improve the enforceability and practicability of the proposed restriction and so support the dynamic and enforceable approach proposed by the Dossier Submitter.  Regarding points 2 and 3, it is unclear what elements of the EEE are affected and what testing the substitution activities will require. In your submission you refer in generic terms to PVC articles and rubber, but no concrete information is provided on the actual EEE parts.  Also SEAC rapporteurs would like to stress that no requests for a longer transition period have been submitted by the manufacturers of materials and components (e.g. cables) during the 6-month consultation on the Annex XV report.  Regarding the derogation for spare parts, SEAC rapporteurs consider that there is no sufficient information on the impacted elements of the spare parts and on whether their production will have to be ceased because of the restriction. Please see the response included at the top of the document as well as the response to comment #1224.  Please also note that the specificity and constraints of each sector were taken into account by the Dossier Submitter and the SEAC to assess the appropriate length of the transition period. SEAC concludes that several alternatives were deemed feasible and available for a large number of applications, with the exception of metal working fluids.  Overall SEAC rapporteurs do not consider that there is a need to modify the opinion based on your comments. |

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| 1234 | Date/Time:  2023/08/11 10:41  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Chloro Alkane Sector Group (a Sector Group of Cefic)  Org. country:  Belgium  Attachment: | General Comments:  We include a PDF document that summarises our comments for consideration. We are the trade association representing the manufacturers of chlorinated paraffins in Europe. |
| Specific information 1:  Please see attached comments |
| Specific information 3:  Please see attached comments |
| Specific information 4:  Please see attached comments |
|  |  | SEAC Rapporteurs response:  Thank you for your comments.  On the first point (“Specific information on socio-economic impacts”), thank you for providing the location of European producers and the approximate annual value of EU MCCP market share. In your comment you also indicate the preparations and articles relying on the use of MCCP will vanish with the proposed restriction, leading to losses of approximately €1 billion per year. Please note that the Dossier Submitter assessed different impacts depending on the restriction option. So, production losses have been also considered in case no derogation is included for metal working fluids. For other uses substitution costs were calculated, considering the available information on alternatives and their economic and technical feasibility.  Regarding the harmonisation between Restriction and POP (point 2), ECHA secretariat will ensure that this comment is duly transferred to the European Commission, for their consideration in the POP discussions.  Regarding your request for a longer transition period for metal working fluids (point 3), please note that the restriction entry in the SEAC opinion has been amended to recommend a 10-year transition period for this use, while also acknowledging that in some circumstances a longer transition period may be required.  Regarding 4th point, the Dossier Submitter noted a lack of communication in the supply chain regarding the presence (or absence) of ‘CA:C14-17 with PBT/vPvB properties’ in other substances, mixtures and articles. During the third call for evidence and when contacting companies during the ECHA market survey, the Dossier Submitter enquired specifically the users of the substances listed in Appendix B.1 and asked them if “they receive from their suppliers any information on the presence and concentration of C14-17 chloroalkanes”. And if not, how the transfer of information in the supply chain could be improved”. In general, the answers to these questions were that such information is not provided, neither in the safety data sheet nor in the technical document accompanying the substance, mixture or article.  With regard to the substance identified as EC 264-150-0 (aka LCCP), where the presence of CA:C14-17 may vary between < 0.1 % and 20 % depending on the quality of the feedstock and the manufacturing conditions, no information on the presence or absence of ‘CA:C14-17 with PBT and/or vPvB properties’ is currently made available to the downstream users. Some downstream users indicated as well that direct contact with their suppliers did not result in additional information on the presence or not of CA:C14-17 with PBT and/or vPvB properties. |

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| 1235 | Date/Time:  2023/08/11 11:22  Type:  BehalfOfAnOrganisation  Org. type:  Company  Org. name:  <redacted>  Org. country:  Germany  Company name confidential:  Yes | General Comments:  No general comments, see specific information request below |
| Specific information 1:  Based on experience, we expect the following periods for product and process changes - Development of new active EP ingredients: 1-2 years - Development of new EP metalworking fluids 1-2 years - Addaption and Approval of the MWF application process at the part and component suppliers: 2-3 years - Approval of the parts in critical industries (aviation, military equipment, medical technology: >5 years |
| Specific information 2:  We are not sure, if punching or stamping oils and oils used for fine blanking are covered by DIN 51385. Therefore these categories should also be included under paragraph 8 of the restriction entry text. |
|  |  | SEAC Rapporteurs response:  Thank you for providing information on the time that you consider is necessary to reformulate metal working fluids with alternatives and specifying which operations may not be covered by DIN 51385.  To ensure that the wording of the derogation covers all the relevant metal working fluids, the opinion has been amended to remove the reference to this DIN.  Regarding the length of the derogation for metal working fluids and having assessed the additional information submitted by parties in the consultation on the Draft Opinion, the opinion has been amended to propose a 10-year transition period for this use. |

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| 1236 | Date/Time:  2023/08/12 17:06  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  EGMF  Org. country:  Belgium  Attachment: | General Comments:  EGMF is the European federation representing major garden, landscaping, forestry, and turf equipment manufacturers. Through its 30 European corporate members and 7 National Associations, EGMF represents about 23 million units placed on the European market in 2021, accounting for around 80% of garden machinery, and EGMF members employ over 120,000 people in the EU.  We are keen to contribute to this consultation but our members have struggled to obtain the necessary information from their supply base in order to answer the questions posed below. We have therefore decided that the best way to respond to this consultation is to submit our position paper instead, and trust that the views expressed in that document will be taken into account.  EGMF stands ready to engage with ECHA and the European Commission if any further consultation is considered. |
|  |  | SEAC Rapporteurs response:  Thank you for your comment.  Regarding the request for derogation for spare parts see the general response included at the top of the document as well as response to comment #1224. Also, from your submission it is not clear what components are affected and whether the whole systems would need to be redesigned to permit the use of the component manufactured with the alternative.  Regarding metal working fluids, SEAC rapporteurs acknowledge that the substitution appears to be challenging on technical and economic grounds, as documented by the stakeholders that participated in the consultation on the Annex XV report and the SEAC Draft Opinion. Having assessed the additional information submitted by parties in the consultation on the Draft Opinion, the opinion has been amended to propose a 10-year transition period for this use.  Regarding your request for a 5-year transition period for garden, landscaping, forestry, and turf equipment, SEAC rapporteurs would like to stress that no requests for a longer transition period have been submitted by the manufacturers of cables, sealants, adhesives, rubber articles, etc during the 6-month consultation on the Annex XV report. Therefore SEAC rapporteurs’ view is that no sufficient information is available in your comment to justify the need for the requested 5-year transition period.  Overall SEAC rapporteurs do not consider that there is a need to modify the opinion based on your comments. |

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| 1237 | Date/Time:  2023/08/14 20:33  Type:  BehalfOfAnOrganisation  Org. type:  Industry or trade association  Org. name:  Independent Lubricant Manufacturers Association (ILMA)  Org. country:  United States of America | General Comments:  The Independent Lubricant Manufacturers Association (“ILMA” or “Association”) submits the following comments to the Committee for Socio-Economic Analysis (“SEAC” or “Committee”) on its draft opinion on the Annex XV dossier (“Proposed Restriction”) that proposes restrictions on medium-chain chlorinated paraffins and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17 (collectively, “MCCPs”).  The Committee, the European Chemicals Agency (“ECHA”), and the European Union (“EU”) member states need to grasp and understand that the adoption of the Proposed Restriction for metalworking fluids (“MWFs”) will result in significant socio-economic harm to the EU, its businesses and workers, its citizens, and its international trading partners.  The Proposed Restriction, if adopted, will eliminate the following metalworking processes in the EU:  • Deep drawing of steel sheets, plates, and bars; • Deep hole tapping of stainless alloys; • Center-less grinding of heat-resistant alloys; • Drawing of certain products; and • Machining of certain products.  SEAC incorrectly and improperly assumes that the derogation periods for water-based and oil-based MWFs will provide manufacturers and their lubricant suppliers with sufficient time to reformulate their MWFs to eliminate MCCPs, including for the above-listed metalworking processes. ILMA’s member companies and their customers, despite years of research with considerable financial expenditures, have been either unable to develop acceptable drop-in substitutes for the above metalworking processes or the substitutes do not work properly across the range of parts made from the same machine. As a result, these metalworking operations across the EU will be forced to close with the attendant economic effects of, and dislocations from, such closures.  Is such a result intended by SEAC and ECHA? Here is a short list of products that will no longer be made in the EU because of SEAC and ECHA’s unfounded decisions: medical devices, such as hypodermic needles, surgical staples, heart stents, and surgical implants (e.g., hips, knees and shoulders); commercial and military aerospace parts (e.g., nuts and titanium bolts and fasteners); ammunition shell casings for civilian, police, and military applications; munitions shell casings; and precision optics. These products, along with others detailed in the subsequent sections of ILMA’s comments, are critical to the EU economy (including jobs), citizens’ health and well-being, and the EU member states’ individual and collective security.  ILMA, UEIL (the Association’s sister organization in the EU), NGOs, suppliers to the Japanese automobile manufacturers, and others have echoed in their comments the dire and unacceptable consequences from the arbitrary derogation periods for MCCPs in MWFs that are not supported by the record in this matter. SEAC and ECHA are ignoring that MCCP uses in MWFs have been, and continue to be, safely managed with recognized wastewater treatment (and discharge limits), and used oil recycling practices. Instead of an unnecessary ban on MCCPs in MWFs with unwanted consequences, SEAC and ECHA instead should focus their regulatory efforts on management standards that promote these environmentally recognized practices.  Based on the following comments, that include the experiences of ILMA member companies and their customers with MCCP-containing MWFs in the United States (“U.S.”), the Association requests that the Proposed Restriction include an indefinite exemption for MCCPs in MWFs, provided that wastewater and used oil recycling management practices and standards are followed.  ILMA, established in 1948, is an international trade association based in the United States that represents over 300 lubricant manufacturers, distributors, and suppliers. ILMA members manufacture lubricant mixtures by compounding and blending components, such as lubricant base stocks and additives, including MCCPs. ILMA members have extensive experience with these substances and their use in MWFs. As a group, ILMA member companies manufacture and sell over 70 percent of the MWFs utilized in North America. Many ILMA members market products internationally either directly, through affiliates, or through distributors, including to the EU.  ILMA members’ extensive experience in formulating MWFs, including those containing MCCPs, enables the Association to offer relevant comments on the Proposed Restriction and its effects on metalworking operations in the EU. MCCPs have been in U.S. and European commerce for decades (over 50+ years), and over this extended period of time, ILMA members have used MCCPs in MWFs as high-quality, cost-effective “extreme pressure” additives used by their customers to cut, draw, and shape metals. ILMA believes its members and their customers responsibly use MCCPs. |
| Specific information 1:  The two- and seven-year derogation periods recommended by SEAC for water-based and oil-based MWFs, respectively, are wholly inadequate. These suggested phase-outs solve nothing, while they only postpone the disastrous socio-economic consequences that will occur. SEAC fails to recognize that MCCP-containing MWFs have been, and can continue to be, safely used to “protect human health and the environment” standards with cost-effective management practices. Therefore, MCCPs used in MWFs should be granted an indefinite exception from the Proposed Restriction. ECHA instead should develop and promulgate enforceable management standards that respect human health, environmental, and business interests. MCCP-containing MWFs are used in machines that perform a range of metalworking processes on a range of metals to make a range of products. For many of these processes, and despite extensive efforts by ILMA members and their customers to reformulate MWFs without MCCPs, MCCPs remain the only viable chemical additives because of their ability to provide lubrication at extreme pressure in machining or forming environments where low boundary lubricant activation temperatures are needed. Based on ILMA members’ experiences and ongoing research, there are metalworking processes for which MWF substitutes without MCCPs will not be feasible for the foreseeable future, including well beyond the seven-year derogation period. If a MCCP ban goes into effect, the machining processes set forth in the chart below will be shut down in the EU. There are no acceptable alternatives. SEAC’s draft opinion fails to account for the socio-economic vulnerabilities and consequences from such forced closures. Based upon data available to the Association and conversations with ILMA members, allied NGOs, and others about the Proposed Restriction, the following metalworking processes would be forced to close, affecting the supply of the products made from those processes: (Metalworking Process. = Non-Exclusive List of Resulting Products.) 1. Processing of stainless steel and high nickel into wire. = Surgical staples and heart catheter devices for medical industry. 2. Processing of stainless steel and high nickel into bars. = Devices used to replace shoulders, hips, knees etc. for medical industry. 3. Centerless grinding of heat resistant alloys. = Parts for aerospace industry. 4. Cold forming of titanium and stainless steel. = Bolts, fasteners, blind rivet shafts, fuel lines, break lines, instrumentation systems, high-pressure conveying systems, and heat exchanger tubing for aerospace industry. 5. Tapping of high nickel-containing alloys and stainless steel. = Nuts for aerospace industry 6. Forming and fabricating of beryllium. = Precision optics for aerospace industry. 7. Drawing of brass shell casings. = Ammunition shell casings for military and civilian use. The importance of these metalworking processes and products cannot be overstated. For example, medical professionals rely on a ready supply of medical devices to treat individuals in their care. The Proposed Restriction would compromise their access to surgical staples, heart catheters, surgical implants, and hypodermic needles — all of which are essential to maintaining the high standards of public health across the EU. By extension, a production halt of these products in the EU would strain worldwide supplies, putting unnecessary pressure on healthcare systems around the globe. How many lives will be endangered when adequate, alternative regulatory approaches exist? Similarly, the aerospace industry depends on parts to build and maintain the EU’s civilian and military aircraft that are manufactured from metalworking processes that use MCCP-containing MWFs. With no acceptable MWF substitutes for the foreseeable future, the Proposed Restriction would affect civilian air travel and freight, and it would compromise the military readiness of EU member states. The same can be said for the manufacture of ammunition and munitions, which depend on MCCP-containing MWFs for the machining of brass shell casings. This is particularly concerning considering the significant military support that EU member states and the U.S. have provided to Ukraine and the growing need for these “donor” states to to replenish their military stores. ILMA recognizes that REACH contains a military exemption; however, ILMA members’ customers cannot easily and quickly change between MCCP-containing MWFs and non-MCCP MWFs based on whether the particular part is going to Airbus for civilian versus military use. ECHA and SEAC assume that the derogation periods offered will spur MWF producers to devise MCCP alternatives — as if MWF producers and their customers have not already made countless attempts to develop such alternatives. ILMA’s member companies have consistently reported that, despite years of time-consuming and expensive research and testing, they have not been able to develop drop-in substitutes for MCCPs in the above-cited metalworking processes. If they could, they already would have. Moreover, while some alternatives have promise, they are less efficient and are not compatible across a range of extreme-pressure machining processes. ILMA held multiple conferences with member companies discussing the Restriction Report and SEAC’s draft opinion. Here is what one member said: "Alternatives – Both centerless grinding and cold forming are done without heating the part. The metal is at ambient temperature at the beginning of each process. During this small amount of time, MCCPs are activated at the metal surface, providing lubrication between part and tool/die. Cutting oils contain other additives such as sulfur, phosphorus and calcium. These additives have specific activation temperatures and chlorine has the lowest. It has been our experience that this “low” temperature zone can only be addressed by chlorine. We have tried to replace chlorine with the additives mentioned as well as high performance esters. None of these have proven to be satisfactory." Other members reiterated that their tribologists have found that there is a limited universe of elements and combined chemistries that can be utilized as extreme-pressure additives in MWFs. Typically-viewed alternatives are chlorinated fatty esters and acids, sulfonated hydrocarbons, phosphate acid esters, phosphorus-containing blends, boundary ester lubricants, complex esters, and nitrogen-containing compounds. Members explained that the main problem with these alternatives is that they are limited in application. For example, sulfur-based chemistries cannot be used in any process involving aluminum because the sulfur will stain the finished aluminum. As another example, using sulfur-based alternatives in the fabrication of stainless steel tubes must be done with extreme care because if any of the sulfur-based compounds remain on the finished product that is subsequently heat treated (i.e., annealed), then the residual sulfur-based materials can cause inner granular corrosion at the grain boundary, which will lead to perforation of the finished, in-service tubes. Changing the composition of a MWF is a time and labor-intensive process. Each fluid must be specially formulated and tested for use in individual machines. Even similar processes (e.g., fabrication and drawing of tube, rod, bar, and wire) require multiple tests and augmentations depending upon the type of machine used for the process. Even the same machine that manufactures the same part that is a few years older requires a specifically tailored fluid that may or may not work in the newer machines. Further, customers must give final approval for the performance of the fluid to ensure the manufactured part is the same finished quality. As a result, fluid changes are a time intensive, expensive, and extensive trial-and-error process. Additionally, MCCP alternatives can only be used when it does not compromise the performance of the MWF for which it is intended. The developer of the alternative fluid must establish that the MCCP alternative provides equivalent or better performance than the current MCCP-containing lubricant. Such performance is based on trials on multiple metals of different sizes. The finished product or part must meet all customer specifications. For example, the following factors are taken into account when formulating and selecting a drawing compound: • Amount of deformation; • Drawing speeds; • Pilger operations; • Tool life; • Tube surface quality; • Post draw cleaning; • Metallurgical damage due to residual elements post annealing; • Compatibility with mechanical systems; and, • Economics. Each of the above factors can be spread across dozens of parts that are made on the same machine. Further, finished products must meet or exceed current acceptable product yield after final testing with no significant rework. To that end, consider the number of parts machined per set of machine tools. One of the benefits of using MWFs fluids containing MCCPs is the remarkably long parts per tool set, particularly with straight oil formulations. One can imagine the cost difference between an MCCP-containing fluid which can machine 200,000 parts per set of tools versus an MCCP-free formulation which can make only 25,000 parts per set of tools. Tooling costs themselves often far outweigh the cost of the fluid. Aside from the difficulty of formulating viable MCCP alternatives, if such alternatives are found, additional time is required often before their use is certified or approved by relevant third parties, such as regulatory authorities. For example, aircraft fasteners, which are manufactured using MCCP-containing MWFs, are subject to rigorous testing and approvals in the U.S. by the Federal Aviation Administration and the U.S. Department of Defense. These regulatory reviews take months and sometimes years to complete. SEAC and ECHA need to factor in the time-consuming approval or certification process across industries using MCCP-containing MWFs. ECHA’s primary motivation for seeking to restrict MCCPs is grounded in environmental concerns. Thus, ILMA’s comments related to the importance of MCCPs in essential machining processes may be given little weight by SEAC because its assumption is that any MCCP use poses an unjustifiable danger to the environment. However, both SEAC and ECHA must recognize that facilities using both water-based and oil-based MWFs with MCCPs have, and continue to, do so under “protect human health and the environment” standards using proper management standards and practices. With respect to water-based MWFs and a two-year derogation, ILMA assumes that ECHA and SEAC believe that these fluids pose a greater environmental risk than their oil-based counterparts. However, start with chemistry: MCCPs are not water-soluble. Even though they remain bound up in oil emulsions in the MWF, the facility where the water-based MWFs are used is subject to existing, fence-line discharge limits for oil and grease. To meet these wastewater discharge limits, facilities use a number of on-site pretreatment and treatment processes to separate oils and greases from the wastewater before its discharge. Once separated from wastewater, the oils and greases are collected and then sent to an offsite specialized treatment facility. Therefore, with such a system in place, any MCCPs in water-based MWFs are separated before they ever leave the facility that uses them in metalworking operations. ILMA assumes that SEAC and ECHA are providing a seven-year derogation period for oil-based MWFs because they pose a lower water contamination risk and are subject to strict used oil recycling standards in the EU. ILMA agrees with this assumption. To illustrate, ILMA’s representatives had an opportunity to visit four metalworking operations in California that use oil-based MWFs with chlorinated alkanes. The representatives were shown how the facilities were set up for what those in the industry call “on-site fluid reprocessing.” Under this process, a used MWF is taken to an on-site fluid recycling unit. This unit removes any solids waste from the fluid, tests the fluid for the proper amount of additives, and then adds the required additives to bring the fluid back to original specifications. The reprocessed oil is then recharged to the machines and reused. The ILMA representatives observed how, because of this process, no used oil-based MWF containing chlorinated alkanes was ever discharged or allowed to enter any sanitary sewer. Instead, the small amounts of water waste generated during the recycling process were collected in reusable totes, which were then sent to a specialized wastewater processing company for treatment. This type of waste disposal practice, performed by these four companies, is exemplary and represents the best practices in handling wastes from metalworking operations. On-site fluid reprocessing allows users of chlorinated MWFs to segregate any chlorine contamination from the facilities’ discharges into sanitary sewers, and by extension, into oceans, lakes, rivers, streams, or publicly owned waste treatment works. Thus, if facilities implement such management practices and procedures, they mitigate any risk of MCCPs water contamination. Therefore, based on the foregoing, an indefinite exemption for MCCP use in MWFs is not only socio-economically beneficial, but any environmental risks associated with MCCPs’ continued use can be mitigated effectively by wastewater management and treatment practices. To that end, ILMA welcomes the opportunity to work with ECHA and SEAC on these cost-effective policies and practices. There is no reason to categorically ban MCCPs in MWFs when other regulatory alternatives – which consider both environmental and business interests – can be pursued. |
| Specific information 3:  ILMA’s comments to Specific Information Request 1 detail how a ban on MCCP use in MWFs will require a number of metalworking processes in the EU to be shut down and will adversely affect the manufacturing of many essential products across Europe — regardless of whether a two- or seven-year derogation period is adopted. To reiterate, when the Proposed Restriction goes into full effect, it will force the following metalworking processes, for which acceptable substitutes for MCCP-containing MWFs are not on the horizon, to close: (Metalworking Process. = Non-Exclusive List of Resulting Products.) 1. Processing of stainless steel and high nickel into wire. = Surgical staples and heart catheter devices for medical industry. 2. Processing of stainless steel and high nickel into bars. = Devices used to replace shoulders, hips, knees etc. for medical industry. 3. Centerless grinding of heat resistant alloys. = Parts for aerospace industry. 4. Cold forming of titanium and stainless steel. = Bolts, fasteners, blind rivet shafts, fuel lines, break lines, instrumentation systems, high-pressure conveying systems, and heat exchanger tubing for aerospace industry. 5. Tapping of high nickel-containing alloys and stainless steel. = Nuts for aerospace industry 6. Forming and fabricating of beryllium. = Precision optics for aerospace industry. 7. Drawing of brass shell casings. = Ammunition shell casings for military and civilian use. The importance of these metalworking processes and products made from them cannot be overstated. To repeat, medical professionals rely on a ready supply of medical devices to treat individuals in their care. The Proposed Restriction would compromise their access to surgical staples, heart catheters, surgical implants, and hypodermic needles — all of which are essential to maintaining the high standards of public health across the EU. By extension, a production halt of these products in the EU would strain worldwide supplies, putting unnecessary pressure on healthcare systems around the globe. Similarly, the aerospace industry depends on MCCP-containing MWFs for parts to build and maintain the EU’s civilian and military aircraft. The Proposed Restriction would affect civilian air travel and freight, and it also would compromise the military readiness of EU member states. Additionally, the Proposed Restriction will result in the closure of machining processes that form beryllium products. Beryllium is used as mirror material in advanced instruments such as satellites, telescopes, and military targeting and firing system — all of which are critical to state-of-the-art civilian and miliary technology in the EU. The same can be said for ammunition and munitions, which depend on MCCP-containing MWFs for the machining of brass shell casings. This is particularly concerning considering the significant military support that EU member states and the U.S. have provided to Ukraine and the growing need to replenish their military stores. ILMA recognizes that REACH contains a military exemption; however, ILMA members’ customers cannot easily and quickly change between MCCP-containing MWFs and non-MCCP MWFs based on the whether the part being made is for civilian versus military use. Because the ban on using MCCP-containing MWFs will cause significant socio-economic harm in the EU, European manufactures will be placed in a competitive disadvantage as higher-priced parts will have to be imported. The costs will be higher in the EU, because global supply chains will be stretched thin, if not broken. This would be harmful enough if the products affected were only used for sophisticated purposes, like military targeting system, which are unlikely to concern the average person. However, MCCP-containing MFWs are used to produce products like hypodermic needles and surgical staples, so the effects of the MCCP ban will be felt through the EU economy. MCCPs used in MWFs should be granted an indefinite exemption from the Proposed Restriction. The negative socio-economic consequences – including on Europe’s manufacturing sector – can easily be avoided if such an exemption is adopted along with appropriate management standards for MCCP-containing MWFs. Moreover, as detailed previously, MCCP-containing MWFs can be safely used when wastewater and used oil recycling management practices and standards are followed. Instead of issuing a broad and arbitrary ban, SEAC and ECHA are in an excellent position to work with the lubricants industry, its customers, and other interested parties to develop management standards and practices that will ensure the ongoing safe and effective use of MCCP-containing MWFs in the EU. |
|  |  | SEAC Rapporteurs response:  Thank you for your technical and detailed comment and responses to SEAC’s questions.  SEAC rapporteurs acknowledge that the substitution in metal working fluids appears to be challenging on technical and economic grounds, as documented by the stakeholders that participated in the consultation on the Annex XV report and on the SEAC Draft Opinion.  Having assessed the additional information submitted by parties in the consultation on the SEAC Draft Opinion, the opinion has been amended to propose a 10-year transition period for this use as well as to acknowledge that this timeframe may not be sufficient for certain categories of metal working fluids. |