**20 DECEMBER 2011**

# ANNEX VI TO RESPONSES TO COMMENTS DOCUMENT (RCOM) ON ECHA'S DRAFT 3RD RECOMMENDATION FOR THE GROUP OF RECOMMENDED CHROMIUM (VI) COMPOUNDS - COMMENTS ON POTASSIUM CHROMATE (EC NUMBER: 232-140-5)

***THIS DOCUMENT PROVIDES THE COMMENTS RECEIVED ON POTASSIUM CHROMATE DURING THE PUBLIC CONSULTATION ON THE 3RD DRAFT RECOMMENDATION FOR INCLUSION OF SUBSTANCES IN ANNEX XIV OF REACH WHICH TOOK PLACE BETWEEN 15 JUNE AND 14 SEPTEMBER 2011. ECHA'S RESPONSES TO THESE COMMENTS ARE PROVIDED IN THE ABOVE MENTIONED RCOM DOCUMENT.***

*N.B.: All public attachments are provided in a separate zip-file available on ECHA's website (attachments claimed confidential are not provided with the public version of this compilation of comments received).*

## I - GENERAL COMMENTS ON THE RECOMMENDATION TO INCLUDE THE SUBSTANCE IN ANNEX XIV, INCLUDING THE PRIORITISATION OF THE SUBSTANCE:

| # | Date (Attachment provided) | Submitted by (name, Organisation/ MSCA) | Comment |
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| 1108 | 2011/09/13 18:01<br><br>File attached | GIFAS<br><br>Industry or trade association France | |

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| 936 | 2011/09/13 13:21 | United Kingdom<br><br><br>MemberState United Kingdom | Based on the prioritisation criteria and the possibility of significant workplace exposure we agree with the proposal to recommend the following substances for inclusion in Annex XIV.<br>Chromium Trioxide<br>Acids generated from Chromium Trioxide and there oligomers.<br>Sodium Dichromate<br>As there is the possibility of substitution to replace other hexavalent chromium compounds, based on the prioritisation criteria and the possibility of significant workplace exposure we agree with the proposal to recommend the following substances for inclusion in Annex XIV.<br>Ammonium Dichromate<br>Sodium Chromate<br>Potassium Dichromate<br>Potassium Chromate |
| 598 | 2011/09/07 15:15 | Company Germany | Chloride determination and the need for the continued use of potassium chromate for analysis purposes.<br>The measurement and control of Chlorides in process waters is essential for the safe operation of boilers and cooling systems. The Chloride level will reveal the presence of dissolved salts in the boiler and an increase, either gradual or sudden, in this level can occur as a result of sudden additions from make-up waters or contaminated treatment chemicals, or gradual accumulations from evaporation. Too high a Chloride level indicates that an undesirable amount of salts is present which can aid corrosion, foaming etc. and can lead to boiler breakdown or failure of cooling systems.<br>It is essential that an easy to use and reliable method of chloride determination is available which lends itself to use within this industry. Users of this test are professional in the sense that they are not members of the general public, are trained in the correct use of the test, and provided with information on the nature of the chemical constituents on the packaging. To allow easy measurement by these professional users, the majority of whom are non-technical personnel, a number of titration based tests have been developed based on liquid drop count chemistries, which give both an easy to read and safe method for the operator. These titration based methods have become the established test in industry world-wide for the accurate control of boilers and cooling system waters.<br>For this type of test to work effectively the inclusion of potassium chromate is essential as a key ingredient. The chemistry behind the method is that the liquid reagent contains a specified amount of Silver Nitrate, plus the indicator (Potassium Chromate). The Silver Nitrate reacts with Chlorides to form insoluble Silver Chloride. Only when all of the Chloride has reacted does the |

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| | | | Silver Nitrate react with the Chromate to give insoluble Silver Chromate, which is red. The number of drops of liquid titrant required until a permanent red colour is given is multiplied by the 'conversion factor' (depending on sample size) to give the Chloride concentration of the sample. The test only works because Silver Chloride has significantly lower solubility than Silver Chromate, so it is totally precipitated before any Silver Chromate is formed. A typical test will only use about 1mg of potassium chromate.<br>Currently there are no alternative methods available suitable for use in measuring boiler or cooling waters by non-technical personnel. Other titration tests based on mercuric nitrate are available but obviously the use of a mercury based chemical is not to be recommended due to its accumulative poisonous effects. Photometric methods do not have a wide enough measuring range to give sufficient accuracy for testing and ion selective electrodes are designed for laboratory testing only, normally require some form of conditioning before use and should be used only by technical personnel and therefore do not lend themselves to on site testing.<br>The consequences of not being able to measure chloride safely, accurately and rapidly are as follows:<br>A)<br>It would lead to a problem with corrosion and therefore an increased cost to industry, due to the failure of boiler and cooling water systems and the increased number of component parts being used. In the worst case, a complete failure and disruption of the boiler or cooling system could occur.<br>B)<br>If frequent, accurate measurement of chloride was not possible this can be countered by the operators through the addition of increased amounts of corrosion inhibitors such as DEHA and Nitrites, again leading to an increase in operating costs, and increased amounts of chemicals within the process water, which ultimately would be discharged into the environment.<br>To help with environmental concerns, the labelling on the packaging could be changed to encourage safe disposal. The operator would be advised that discarded containers and used samples should be placed into bonded containers after use for safe disposal via a recognised waste disposal service.<br>The lack of a rapid and accurate method for the measurement of chloride would have significant implications in process water management, and with no alternatives available, the lack of control, the increased failures and increased use of corrosion inhibitors would lead to additional costs to both industry and the environment. |

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| 1788 | 2011/09/14 19:53 | European Federation pf Pharmaceutical Industries and Associations<br><br>International Organisation Belgium | EFPIA has noted with interest the call by ECHA of June 2011 for comments on proposals to include a number of new substances, including Potassium Chromate, in Annex XIV of the REACH Regulation as substances of very high concern (SVHCs) which would require authorisation for their use.<br>A number of these substances, including potassium chromate, have critical uses in the research, manufacture and control of medicinal products for which there are, at this time, no practical alternatives.<br>The details realting to potassium chromate and its uses are set out below and EFPIA asks that, if it is to be included in Annex XIV, it be exempted from the necessity for authorisation for use in research, development, manufacture or anlytical control of medicinal products and their ingredients and for any corresponding uses in relation to medical devices. |
| 979 | 2011/09/13 14:51 | AREVA<br><br>Company France | Laboratory measurment for quality reasons and/or monitoring of release require uses of such substances. It should be clearly stated that such used are exempted of authorization process. |
| 676 | 2011/09/09 13:06 | Hach Lange GmbH<br><br>Company Germany | Potassium chromate is a compound that is used in laboratory analysis for different reaction. For example, it is used in reagent sets for the determination of Chloride by argentometric titration with silver nitrate. The application is for laboratory and field analysis, and ready for use. The advantage of the reagent set is, that the risk of contamination by the noxious substances, is low for the user. It is effectively a closed system, since the user only has to add the water sample once. Accordingly, the risk of coming into contact with the reagent is very low.<br>Compared with the conventional reference procedures, the regents set needs less pollutants, and a correspondingly smaller quantity of Potassium chromate.<br>Therefore, it is essential to exempt the use of Potassium chromate for “analysis purposes” respective “laboratory uses” from the requirement for approval, or it should be classified as an approved use. |

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| 1662 | 2011/09/14 16:39 | Council of Europe, Directorate for the Quality of Medicines and HealthCare<br><br>International Organisation France | Potassium chromate is used in the European Pharmacopoeia. The quality of medicines including their containers and raw materials may be compromised, if it is withdrawn from the market. |
| 1596 | 2011/09/14 14:59<br><br>File attached<br>Confidential | Company United Kingdom | The aerospace industry is heavily regulated by CAA and EASA having to conform to extremely rigorous standards. Product safety is of paramount importance and alternatives with reduced performance would be totally unacceptable.<br>Alternatives to Potassium Dichromate have actively been investigated for many years but it is still widely used because of its superior corrosion performance for a broad range of applications. In many cases, no direct safe alternatives either do exist or indeed may ever exist due to the unique nature of Chromium Chemistry amongst the Transition metals capable of higher integer oxidation states.<br>While similar physical behaviours have been observed in other elements, none come close to those of chromium and particularly the transition metal chromate's ability to provide long-term corrosion protect and self-healing corrosion prevention mechanisms for substrates. Even closely related elements within the Periodic Table fall far short of this ability to form tenacious and self healing surface layers.<br>Potassium dichromate has performed effectively in service for more than half a century, with characteristics that few other surface treatment chemicals can match. Its wide general oxidising power has been applied to surface processing for corrosion protection and to prepare such surfaces for even more robust, multi-stage corrosion protections. To develop this level of understanding of service envelopes and performance limits of other materials suggested as alternatives will require a similar period of development and testing.<br>In addition, chromium VI compounds are extremely effective because of their ability to protect areas where damage has occurred.<br>For these reasons, it is essential that prioritisation be deferred for as long as possible, to allow |

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| | | | time for alternative solutions to become fully tested and accepted for safety and airworthiness. Without this additional time, it is anticipated that there will be extensive applications for authorisation to continue to use potassium dichromate if it appears on Annex XIV. The level of effort that will be expended in making these applications could be better employed in sorting out the qualification and introduction of safe and effective alternatives.<br>An additional reason for deferring the prioritisation of potassium dichromate is the need to allow sufficient time for the formation of suitable aerospace and defence consortia, involving participants from all levels of the supply chain. This is essential if comprehensive applications for Authorization are to be made. |
| 673 | 2011/09/09 12:47<br><br>File attached | Company<br>Germany | The criteria for prioritization of substances for inclusion into Annex XIV are listed in Art. 58 (3):<br>a) PBT or vPvB properties, or<br>b) wide dispersive use, or<br>c) high volumes.<br>None of these criteria applies to potassium chromate. As mentioned in the background document, the volume of potassium chromate manufactured in the EU is quite low and the uses of the substance are not considered as wide dispersive.<br>Nevertheless, we understand the need for the authorisation of potassium chromate (regulatory effectiveness) to prevent the switch from hexavalent chromium compounds, which is fulfilling the criteria of Art. 58 (3), to potassium chromate for some uses. However, this should not lead to authorization for uses of potassium chromate which are not related to this regulatory effectiveness and which would not have been in focus of authorization based solely on the criteria of Art. 58 (3).<br>Potassium chromate is an important substance for scientific research and development, which is performed in the pharmaceutical industry and in routine analytics. It is actually not possible to replace potassium chromate in these applications. |

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| 669 | 2011/09/09 12:39<br><br>File attached | Company<br>Germany | The criteria for prioritization of substances for inclusion into Annex XIV are listed in Art. 58 (3):<br>a) PBT or vPvB properties, or<br>b) wide dispersive use, or<br>c) high volumes.<br>None of these criteria applies to potassium chromate. As mentioned in the background document, the volume of potassium chromate manufactured in the EU is quite low and the uses of the substance are not considered as wide dispersive.<br>Nevertheless, we understand the need for the authorisation of potassium chromate (regulatory effectiveness) to prevent the switch from hexavalent chromium compounds, which is fulfilling the criteria of Art. 58 (3), to potassium chromate for some uses. However, this should not lead to authorization for uses of potassium chromate which are not related to this regulatory effectiveness and which would not have been in focus of authorization based solely on the criteria of Art. 58 (3).<br>Potassium chromate is an important substance for scientific research and development, which is performed in the pharmaceutical industry and in routine analytics. It is actually not possible to replace potassium chromate in these applications. |
| 1130 | 2011/09/13 18:21 | Agoria<br><br>Industry or trade association<br>Belgium | The prioritization of the different chromium compounds does not seem appropriate for Agoria. Their classification make these chromium compounds eligible to be prioritized but there are doubts on the claimed widespread use of these chromium compounds as well as on the exposure which has an impact on the prioritization.<br>The exposure on the workplace is limited given the precautionary measures taken due to the toxic nature of the chromium compounds. Several elements should be taken into account such as the type of installation level, the exact number of people exposed as well as the in general low level of exposure and the lack of consumer exposure.<br>The installations used within industry are designed to limit strongly the potential exposure of workers to the maximum. Different concepts are existing through either the use of closed full automatic installations, collective protection equipment such as the suppression of chromate vapors by a mist or by the use of adequate individual protection equipment linked to an appropriate internal organization together with all other eventual measures.<br>The number of workers exposed is much more limited than supposed in the annex XV document, given that in several companies the chrome unit is only a limited part of the installation and not all workers are active/exposed in it. In some companies the chrome unit is only one, yet vital, processing unit, with a limited number of staff exposed (sometimes a range of less than 10 workers potentially exposed to the chromium unit compared to 500 to 4.000 workers for the |

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| | | | complete plant). Our estimation in Belgium is that approximately 300 workers are exposed to chromates, max. 200 in hard chrome and decorative chromium plating and max 100 in passivation with chromium VI compounds. The total employment concerned within the global supply chain, including the indirect employment is however much higher as indicated already above. Given that the process is in certain installations linked to the production of highly complex products, the socio-economic impact can be much higher. In certain cases the complete industrial installation can become obsolete if this essential production step cannot be done anymore due to a lack of authorization. Finding proper alternatives for chrome in plating, taking into account the broad technical properties of chrome in the surface protection as well as the economical viability is rather difficult as otherwise these alternatives would have already been put in practice. Chrome plating is most vulnerable since there is no authorisation required to import chrome plated parts.<br>The exposure level is in general lower than the data used in the Annex XV dossier. Agoria estimates, based upon some measurements and medical follow-up in companies, the general level of exposure between 0,01-0,001 mg/m3 well below the level which is in general put forward as limit value at Belgian level (0,05 mg/m3). Sometimes, the measurements of chromium in the environment is suspended given that these measurements are below the detection limit and only bio-monitoring (urine) is used as a proper follow-up of exposure. The values in the annex XV dossier, are also critically reviewed by a Fraunhofer report commissioned for ZVO (see: http://www.zvo.org/uploads/media/Chromtrioxid_SVHC__2011-09-05_Final_EN.pdf)<br>and concludes that the quality of the data used in the report can be questioned and yet they are used to extrapolate the situation not only at German level but more broadly on an European level in order to prioritize these chrome compounds.<br>On the level of consumer exposure one should clarify that the final hard chrome plated product does not contain any chrome VI components given that they are all transformed during the plating process into hard chrome metal. Exposure of end consumers from hard chrome plating does therefore not exist for this surface treatment technology. An important point regarding chromates is the factor that the chromium VI is between the article and the plating which reduces the potential of exposure and the chromium VI oxides very quickly in a corrosion process or in contact with any organic material. We therefore believe that the factor wide dispersive use for the prioritization should take into account these elements in order to create a more correct view on the prioritization needed for these substances.<br>In the annex XV dossier some alternatives are described but these are in our view not well documented. Important elements which are lacking are amongst others: |

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| | | | - The economic feasibility of the substitution linked to the factor that imported articles with chrome plating will remain a fact after the sunset date,<br>- The technological challenge including the economic costs for re-designing products as well as production facilities given that complete new installation have to be put in place for the alternatives,<br>- The technical properties of the substitution including long term behavior and certification.<br>In different current markets, such as automotive, off-road vehicles, aeronautic applications, … with strong, long term quality guarantees, security issues and very stringent certification obligations. This increases the technical challenges of any substitution program,<br>In fact several worldwide research activities were conducted in the past already for the substitution of chromium without any major success. (Ecochrom, HCAT, JCAT…) Technologies which are mentioned in the annex XV file do not permit the substitution of an important part of the use for chromium six compounds for chromate passivation, chromic anodizing and chrome plating.<br>A first and limited overview of some typical alternatives put forward for hard chrome:<br>Thermal spray and HVOF: These technologies are not available for deposits less than 80 microns. Thermal spray doesn't permit treating pieces with complex size and geometry. Thermal spray is only adapted for the production of single pieces and mass production is not possible. Hard chromium plating stays a surface treatment process without alternative options for at least 70% of these applications (aerospace application, mechanical, nuclear, alimentary compatibility…) and this without considering costs.<br>Vacuum coatings: Vacuum coatings are realized in closed containments. The thickness of deposits can't exceed 5 microns. This technology does not provide a proper corrosion protection. The time to realize deposit makes vacuum coatings for mass production economically and technically impossible. Moreover, the cost of the coatings is three times more expensive than a surface treatment realized by a wet process such as chromium plating including state of the art water and air treatment.<br>Zinc based alternatives: zinc coatings are offer cathodic corrosion protection which means that they dissolve themselves in order to protect pieces against corrosion. So, coating thickness is very important in order to provide the necessary corrosion protection over a given time period. Chromium coatings offer anodic protections. The coating isn't dissolved over the time of corrosion protection which assures a good durability of the corrosion protection of the product. Zinc based alternatives haven't the same technical characteristics than coatings made with chromium six compounds (hardness, wear resistance, coefficient of friction, anti-sticking properties…) |

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| | | | Nickel based alternatives: Electroless nickel offers interesting properties and these are probably maximally exploited. Limits are hardness (highest hardness requires heat-treatment), less anti-adhesive, risk for porosity, less suited and prohibitive costs for thickness >30 µm, slow process, outperformed by chromium in lubricated conditions (hydraulics), costly process (difficult to control and continuously changing composition), use of soluble nickel salts, …<br>Chromium III coating: chromium deposits realized with trivalent chromium are possible for decorative coatings, with low thickness (typically < 0.5 µm). It is impossible to obtain deposit with big thickness achieving the technical performance hard chromium plating. This technology needs three chromium baths and its technical implementation is much more difficult than baths with chromium six. The deposit cost is also multiplied by a factor three.<br>Part modification: in this case there is a need to replace material such as titanium, plastic, aluminum by steel which can be heat-treated. In most cases the weight is an issue and the pieces in aeronautic must be the most lightest possible to answer the technical challenge and makes this alternative technically not possible. Moreover heat-treatment causes variation on the part's dimensions which is incompatible with the final utilization's pieces.<br>It is important to remember that all these alternatives do not cover all the applications obtained by chromium six compounds. Many applications are not mentioned in the annex XV document. This is the case for black chromium, stripping of plastics, conversion of stainless or cadmium for which no alternative exist today. |
| 904 | 2011/09/13 12:00 | The Tintometer Ltd.<br><br>Compay<br>United Kingdom | Use of small amounts of potassium chromate for analysis purposes should be exempted from inclusion. |
| 1093 | 2011/09/13 17:48 | Germany<br><br>MemberState<br>Germany | We support the ECHA proposal on prioritisation of potassium chromate. |

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| 981 | 2011/09/13 14:50 | Sweden<br><br>MemberState<br>Sweden | We support the prioritisation of potassium chromate for inclusion in Annex XIV even though the scoring approach results in low priority. As chromium (VI) compounds have partially the same uses and could be replaced by each other a grouping approach is warranted. |
| 551 | 2011/08/24 14:08 | WWF European Policy Office<br><br>International NGO<br>Belgium | WWF supports the prioritisation for inclusion in Annex XIV due to the fact that it could be used to replace other hexavalent chromium compounds with similar hazard profile and similar uses. |

**II - TRANSITIONAL ARRANGEMENTS. COMMENTS ON THE PROPOSED DATES:**

| # | Date (Attachment provided) | Submitted by (name, Organisation/ MSCA) | Comment |
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| 598 | 2011/09/07 15:15 | Company<br>Germany | Application date: 2021<br>Sunset date: Application date + 18 months<br>National and international normations most likely will not be changed in a shorter period of time. |

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| 1596 | 2011/09/14 14:59<br><br>File attached<br>Confidential | Company<br>United Kingdom | If ECHA follow previous practice, it is likely that potassium dichromate will enter Annex XIV in January 2013, with a likely "Sunset date" of 4 years later, in January 2017. However, applications for Authorisation for the continued use of potassium dichromate would have to be completed and submitted 18 months before the "Sunset date"; July 2015 by the latest. This represents insufficient time to complete the necessary R&D programmes required to produce qualified alternatives to potassium dichromate. An extension of several years is necessary to assure that the rigorous safety and airworthiness criteria can be met with alternative substances. |
| 551 | 2011/08/24 14:08 | WWF European Policy Office<br><br>International NGO<br>Belgium | The timelines foreseen for transitional arrangements should be shortened to an application date of 12 months (sun set date 30 months) after the date of inclusion in Annex XIV |
| 1130 | 2011/09/13 18:21 | Agoria<br><br>Industry or trade association<br>Belgium | The timing of the deadline for exemptions will be extremely ambitious for different companies given that there is at this moment still a need for a better cooperation between industry partners within the chain. This is mainly due to on the one side a lack of real producers of these compounds within Europe and on the other side the broad range of different applications, sectors for which it will be a challenge to work out together the authorization dossier. An extension of the deadline would help to bring together these different industry sectors in order to work on a common authorization dossier and thus improving the quality of the dossier as well as lowering the administrative burden for the evaluation.<br>We therefore ask for an extension of the deadline for the submission of the authorization dossiers with 12 months and consequently also the extension of the sunset date by 12 months. |

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| 892 | 2011/09/13 11:47 | European Aviation Safety Agency<br><br>European Institution Germany | This chemical substance is used in manufacturing and or maintenance of aviation products and parts. It might not be easy to find an alternative substance that would have the same attributes and or performance and the banning of such substance may therefore have a negative impact on aviation safety. We invite the ECHA to consider a possible exemption for the use in aviation applications or an appropriate transition period. The European Aviation Safety Agency is willing to contribute to a discussion on such exemption or transition. |
| 981 | 2011/09/13 14:50 | Sweden<br><br>MemberState Sweden | We agree with the proposed dates. |

**III - COMMENTS ON USES THAT SHOULD BE EXEMPTED FROM AUTHORISATION, INCLUDING REASONS FOR THAT:**

| # | Date (Attachment provided) | Submitted by (name, Organisation/ MSCA) | Comment |
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| 1753 | 2011/09/14 18:52 | Association of the British Pharmaceutical Industry<br><br>Industry or trade association | ABPI has noted with interest the call by ECHA of June 2011 for comments on proposals to include a number of new substances, including Potassium Chromate, in Annex XIV of the REACH Regulation as substances of very high concern (SVHCs) which would require authorisation for their use.<br>A number of these substances, including potassium chromate, have critical uses in the research, manufacture and control of medicinal products for which there are, at this time, no practical alternatives.<br>The details realting to potassium chromate and its uses are set out below and ABPI asks that, if it is to be included in Annex XIV, it be exempted from the necessity for authorisation for use in research, development, manufacture or anlytical control of medicinal products and their |

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| | | United Kingdom | ingredients and for any corresponding uses in relation to medical devices.<br>This should cover the steps starting from manufacture of the substance (already exempted), filling into packages, preparation of formulations described in standards (DIN, EN, ISO and ASTM), Pharmacopoeias (Reag. Ph. Eur. and ACS) till the use as calibration standard for ICP and AAS. The use of these formulations for scientific R&D (< 1t/a) is already exempted.<br>The criteria for prioritization of substances for inclusion into Annex XIV are listed in Art. 58 (3):<br>a) PBT or vPvB properties, or<br>b) wide dispersive use, or<br>c) high volumes.<br>None of these criteria applies to Potassium Chromate. As mentioned in the background document, the volume of Potassium Chromate regulated by the authorization in the EU is quite low and the uses of the substance are not considered as wide dispersive.<br>Nevertheless, we understand the need for the authorization of Potassium Chromate (regulatory effectiveness) to prevent the switch from other salts salts, which are fulfilling the criteria of Art. 58 (3), to Potassium Chromate for some uses. However, this should not lead to authorization for uses of Potassium Chromate which are not related to this regulatory effectiveness and which would not have been in focus of authorization based solely on the criteria of Art. 58 (3).<br><br>Use as an analytical reagent<br>Potassium chromate is an important substance for scientific research and development, which is performed in the pharmaceutical industry and in routine analyses. It is actually not possible to replace potassium chromate in these applications.<br>Liquid potassium chromate formulations are used as analytical reagent, e.g. as volumetric solution or for the standardization of volumetric solutions and instruments in the pharmaceutical industry and ISO-certificated labs.<br>Potassium chromate formulations for standardization purposes and as analytical reagent are prescribed in the European Pharmacopoeia (Ph. Eur.), in the US Pharmacopoeia (USP), and in the ACS.<br>The usage of potassium chromate is still state of the art, no alternative methods are available. At the moment there is no evidence, that either the European or the US Pharmacopoeia is seeking for alternatives to potassium chromate formulations.<br>ISO-certified labs and pharmaceutical quality control labs in the EU are obliged by governmental organizations (e.g. FDA) to perform the calibration of UV/VIS photometer on a regular basis and therefore have the need to use potassium chromate formulations. |

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| | | | All formulations mentioned in the uses described above are used in the laboratory by industrial and professional users that are well-trained. The concentration used in these formulations is low (up to<br>0.5 % as a maximum), the volume needed for one analysis/calibration is in the range of volumes used in the laboratory.<br>According to our knowledge the majority of the potassium chromate formulations used for calibration purposes and as analytical reagents are disposed of in line with current legislation.<br>This reagent is used in the preparation of Potassium Chromate Solution R. This solution has specific uses in the identity tests for the 3% and 30% hydrogen peroxide monographs, the assay procedure for the chloral hydrate monograph, and in the determination of sodium chloride in the Sodium Lauryl Sulfate, Dextran 1 for Injection and Sodium Cetostearyl Sulfate monographs. Potassium Chromate Solution R is also used in the soluble chlorides test in the Magaldrate monograph.<br>Significance of the European Pharmacopoeia<br>The European Pharmacopoeia (Ph. Eur.) is prepared under the authority of the Council of Europe. The governments of Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, 'the former Yugoslav Republic of Macedonia', Turkey and the United Kingdom currently recognize the European Pharmacopoeia. Articles (drug substance or excipients) covered by a Ph. Eur. monograph must meet the requirements of the monograph, including any applicable general tests referenced by the monograph in order to be legally marketed or used in a marketed medicinal product. |
| 598 | 2011/09/07<br>15:15 | Company<br>Germany | Exempted uses should be as follows: SU3, SU9, SU10, SU22, SU24, PC21, PROC3, PROC5, PROC8a, PROC9, PROC14, PROC15, PROC19, ERC2<br>Annual consumption: Less than 1000 kg |

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| 676 | 2011/09/09 13:06 | Hach Lange GmbH<br><br>Company Germany | It is essential to exempt the use of Potassium chromate for “analysis purposes” respective “laboratory uses” from the requirement for approval, or it should be classified as an approved use. |
| 1857 | 2011/09/15 09:32 | Company Germany | Kaliumchromat ist eine Stoff der für verschieden analytische Bestimmungsverfahren europaweit verwendet wird, die gesetzlich vorgeschrieben sind. Besonders hervorzuheben sind hier die Bestimmung des chemischen Sauerstoffbedarf in Wasser und Abwasser (CSB) nach DIN 38409 bzw. EN ISO 15705 und die Arzneimittelanalytik nach European Pharmacopoeia 7.0.<br>Die CSB Bestimmung ist eine europaweit angewendete Methode im Bereich Abwasser Behandlung und Kontrolle, die in vielen gesetzlichen Vorschriften vorgeschrieben wird und von allen öffentlich-rechtlichen, staatlichen und privaten Laboratorien verwendet wird. Zur Zeit gibt es keine etablierte alternative Methode ohne Chromat zur Bestimmung oxidierbarer Stoffe im Wasser.<br>Die Verwendung von Kaliumchromat in diesen Bereichen der Analytik und Forschung erfolgt in der Regel durch qualifiziertes Fachpersonal und unter kontrollierten Laborbedingungen. Eine geregelte Entsorgung in den Laboratorien bzw. durch Rücknahme und Aufarbeitung der Abfalllösungen durch die Hersteller schließt eine Umweltexposition<br>Die dargelegten Verwendungen genügen den Anforderungen des Art.58(2) für eine sichere Verwendung die von der Zulassung ausgenommen werden kann. Um die Versorgung aller europäischen analytischen Laboratorien mit Reagenzien und Lösungen sowie Standards für die Chromatbestimmung zu gewährleisten sollte die Verwendung als Analytisches Reagenz durch professionelle Verwender von der Autorisierung ausgenommen werden. Ohne eine explizite Freistellung dieser Verwendung wird es unweigerlich zu großen Problemen bei der Routineanalytik von Wasser und Arzneimitteln kommen. |

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| 904 | 2011/09/13 12:00 | The Tintometer Ltd.<br><br>Company United Kingdom | Public Consultation on the inclusion of potassium chromate to the Authorisation list<br>Chloride determination and the need for the continued use of potassium chromate for analysis purposes<br>The water treatment market will grow at an annual rate of 5.7% through 2013, reaching a value of $58.7bn, according to market research firm The Freedonia Group, a leading international business research company, with chemicals making up a huge 30.6%.<br><br>Application specific chemicals are formulated and developed by specialist companies and marketed, sold and supported globally. Industrial water treatment companies use or blend these chemicals to sell full treatment and maintenance programs for a range of power plant and process water systems. Whilst there are ongoing efforts to introduce environmentally friendly treatments, many hazardous/harmful scale and corrosion inhibitors are used extensively for both land based applications and at sea by the world's merchant fleet.<br>For marine applications:<br>Treatments are supplied as concentrates in 25-200L containers and used on either a continuous basis or via timed dosing pumps. Typical chemical consumption for a vessel of 35,000 tonnes fitted with a main engine cooling system of 5-8 tonnes and a LP 30Bar steam boiler of 10-12 tonnes is as follows:<br>Nitrite Inhibitor 100-400 L per annum<br>Sulphite Inhibitor 200-400 L per annum<br>Caustic/phosphate 400-600 L per annum<br>Concentrates range from 40-100% active and contain compounds such sodium hydroxide, hydrazine, activated sulphite, sodium nitrite etc...<br>All treatments have optimum dose rates to give the desired performance. Deviation reduces the effect of the additive. Under-dosing leaves a system under-protected. Scale, corrosion or microbiological fouling can occur, reducing efficiency and increasing maintenance. Over-dosing unnecessarily increases chemical usage, but can also increase corrosion rates.<br>A quote from Nancy White of GE Power & Wind taken from the C&I Magazine, Issue 3, 2010 Water Treatment Works by Cynthia Challener, 07/02/2011<br>(GE being a global market leader in specialist water treatment chemicals)<br>`Industry needs to optimise performance for continually changing operating conditions. Combining chemical and non-chemical treatments with effective monitoring systems makes it possible to manage cost and performance so that the treatment solution is a proactive one rather than a reactive one,' observes Nancy White, general manager of product management water services for GE Power & Water. The result is the ability to achieve higher cycles of concentration |

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| | | | through optimised scale, corrosion and microbiological control.<br>Marine engine cooling systems are treated with corrosion and scale inhibitors. Any salt water ingress into the cooling system will introduce chloride ions, dramatically increasing the corrosive nature of the water. Failure to dilute with fresh water and re-dose with inhibitor will have a catastrophic effect on the performance and lifespan of the engine. Daily testing and recording of chloride ion concentration is standard industry practice. Log books are inspected regularly to ensure chloride ions are below specified levels.<br>Engine room personnel are not chemists, so rely on simple chemical kits developed by The Tintometer Ltd. and other kit manufacturers to determine chloride ion concentration. The industry standard, reliable procedure involves the use of potassium chromate as the indicator in an argentometric titration at neutral pH. Precipitated orange/brown silver chromate indicates the endpoint of the test, following titration of all chloride ions. The test works because silver chloride has significantly lower solubility than silver chromate, so it is totally precipitated before any silver chromate is formed.<br>Reagents are packaged as 100mg tablets sealed in blister packs or supplied in bottles, usually of 250 tablets. Other kits use liquid reagent in 30ml or 65ml plastic dropper bottles. Both provide the operator with small quantities of safe to handle product for performing this critical test in what can be difficult or confined work spaces. These titration based methods have become the established test within the marine industry and are now widely used throughout the world in all aspects of cooling and boiler water testing.<br>Steam boilers are extensively used in the merchant fleet, providing power throughout the vessel. Chloride determination is essential for assessing the ongoing performance of the steam boiler. Cycles of water concentration are calculated using the results of the chloride test and regular monitoring will also alert the operator to the presence of sea water chloride from contaminated feed. Excessive chloride again induces corrosion, but also adds to the dissolved solids in the boiler to cause foaming and boiler water carry over. Efficiency is lost and blow down necessary to remove the contaminants. Re-dosing with inhibitor would then be necessary.<br>There are three standard methods for the determination of chloride ions:<br>1. Silver nitrate/potassium chromate<br>2. Acidified permanganate<br>3. Mercuric nitrate/diphenylcarbazone<br>Acidified permanganate method is fraught with interference problems when measuring chloride in these environments. The mercuric nitrate method is used, but many companies already have policies that ban the use of mercury containing compounds, so moving to this technique would seem a backward step. The only viable alternative is the reliable and accurate silver |

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| | | | nitrate/potassium chromate chemistry used globally to date. Any other complex laboratory based methods such as ion selective electrode determination are simply not suited to the conditions and operator ability.<br>Banning the use of potassium chromate for the purposes of safe, accurate and rapid chloride testing on boiler and cooling water would have the following consequences:<br>A) Potential increases in corrosion rates for boilers and cooling systems, reducing lifespan of plant and increasing maintenance and down time.<br>B) Risk of boiler explosion through failed/corroded parts.<br>C) Operators would increase the quantities of corrosion inhibitors as a "fail safe" measure of chloride protection. Over dosing inhibitors such as DEHA and nitrites lead to increased amounts of chemicals within the process water and ultimately increased levels of chemical in environment (following boiler blowdown).<br>As a responsible supplier of water testing reagents to industry, we have already introduced a returns system to aid the safe disposal of potassium dichromate wastes from COD vials used in the determination of wastewater chemical oxygen demand (COD). The Tintometer Ltd. would alter labelling to encourage safe disposal.<br>In summary, the lack of a rapid and accurate method of chloride determination would alter the working practices of the global marine merchant fleet; from a "treat on demand" policy, to "chemical overdose" in order to ensure corrosion protection. The environmental impact of such practices requires serious consideration before any decisions are made on the banning of potassium chromate from industrial use in chloride determination. It should also be noted that a chloride test typically uses just 30mg of chromate per test. A vessel would usually perform 1 test per day. Compare this with the additional 100-200 litres of chemical treatment used if, at a very conservative estimate just 15% overdose occurred per year.<br>The Tintometer Ltd. requests that the use of safely packaged, small units of potassium chromate reagent continues to be permitted for analysis purposes, principally to support industrial and marine cooling and boiler systems. |
| 673 | 2011/09/09 12:47<br><br>File attached | Company<br>Germany | Request:<br>We suggest to exempt from the authorization requirement the filling and placing on the market of solid potassium chromate solely for the supply to industrial and professional users for scientific research and development. The exemption is required e.g. to secure the supply of medicinal products worldwide and to secure routine analytics and scientific research and development done in laboratories worldwide.<br>Background: |

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| | | | Potassium chromate is described in the reagent part of the European Pharmacopoeia.<br>Solid potassium chromate is also used as an oxidizer in laboratory applications.<br>Solid potassium chromate in analytical grade is mainly used to prepare liquid potassium chromate formulations. Liquid potassium chromate formulations are used as analytical reagent, e.g. as volumetric solution or for the standardization of volumetric solutions and instruments in the pharmaceutical industry and ISO-certificated labs, and in routine analytics for quality control of raw materials and finished products.<br>Potassium chromate formulations for standardization purposes and as analytical reagent are prescribed in the European Pharmacopoeia (Ph. Eur.), in the US Pharmacopoeia (USP), and in the ACS.<br>The usage of potassium chromate is still state of the art, no alternative methods are available. At the moment there is no evidence, that either the European or the US Pharmacopoeia is seeking for alternatives to potassium chromate formulations.<br>ISO-certified labs and pharmaceutical quality control labs in the EU are obliged by governmental organizations (e.g. FDA) to perform the calibration of UV/VIS photometer on a regular basis and therefore have the need to use potassium chromate formulations. It is also used in quantitative trace analysis, often in environmental analysis. Furthermore potassium chromate is used as an oxidizing agent in laboratory applications.<br>All formulations mentioned in the uses described above are used in the laboratory by industrial and professional users that are well-trained. The concentration used in these formulations is low (in most cases up to 0.5 % as a maximum), the volume needed for one analysis/calibration is in the range of volumes used in the laboratory.<br>According to our knowledge the majority of the potassium chromate formulations used for calibration purposes and as analytical reagents are disposed of in line with current legislation.<br>Therefore, we suggest that not only the use of potassium chromate in scientific research and development but also the refilling to supply into these R&D applications should be exempted from authorisation. |

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| 669 | 2011/09/09 12:39<br><br>File attached | Company<br>Germany | Request:<br>We suggest to exempt from the authorization requirement the preparation and placing on the market of liquid potassium chromate formulations solely for the supply to industrial and professional users for scientific research and development. These formulations will only be supplied in packages used in laboratories, e.g. sealed cuvettes, ampoules or bottles. The exemption is required e.g. to secure the supply of medicinal products as well as the quality check of instruments which are used for the control of medicinal products worldwide and to secure routine analytics done in laboratories worldwide.<br>Background:<br>Liquid potassium chromate formulations are used as analytical reagent, e.g. as volumetric solution or for the standardization of volumetric solutions and instruments in the pharmaceutical industry and ISO-certificated labs, and in routine analytics for quality control of raw materials and finished products.<br>Potassium chromate formulations for standardization purposes and as analytical reagent are prescribed in the European Pharmacopoeia (Ph. Eur.), in the US Pharmacopoeia (USP), and in the ACS.<br>The usage of potassium chromate is still state of the art, no alternative methods are available. At the moment there is no evidence, that either the European or the US Pharmacopoeia is seeking for alternatives to potassium chromate formulations.<br>ISO-certified labs and pharmaceutical quality control labs in the EU are obliged by governmental organizations (e.g. FDA) to perform the calibration of UV/VIS photometer on a regular basis and therefore have the need to use potassium chromate formulations. It is also used in quantitative trace analysis, often in environmental analysis. Furthermore potassium chromate is used as an oxidizing agent in laboratory applications.<br>All formulations mentioned in the uses described above are used in the laboratory by industrial and professional users that are well-trained. The concentration used in these formulations is low (up to<br>0.5 % as a maximum), the volume needed for one analysis/calibration is in the range of volumes used in the laboratory.<br>According to our knowledge the majority of the potassium chromate formulations used for calibration purposes and as analytical reagents are disposed of in line with current legislation. Therefore, we suggest that not only the use of potassium chromate in scientific research and development but also the formulation and the filling to supply into these R&D applications should be exempted from authorisation. |

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| 1596 | 2011/09/14 14:59<br><br>File attached<br>Confidential | Company<br>United Kingdom | The primary use of potassium dichromate in aerospace and defence applications is to contribute to the corrosion protection scheme of the aircraft and its safety in flight. This is required to function for the life of the aircraft, which may be over 40 years. Corrosion protection is an essential defence mechanism for metallic components that are built into the structure of the aircraft and may be inaccessible in terms of easy maintenance. For this reason, many of the applications can be considered to be Safety Critical Applications. All such applications of potassium dichromate should be exempt from the requirements of Annex XIV. |
| 892 | 2011/09/13 11:47 | European Aviation Safety Agency<br><br>European Institution<br>Germany | This chemical substance is used in manufacturing and or maintenance of aviation products and parts. It might not be easy to find an alternative substance that would have the same attributes and or performance and the banning of such substance may therefore have a negative impact on aviation safety. We invite the ECHA to consider a possible exemption for the use in aviation applications or an appropriate transition period. The European Aviation Safety Agency is willing to contribute to a discussion on such exemption or transition. |
| 1788 | 2011/09/14 19:53 | European Federation pf Pharmaceutical Industries and Associations<br><br>International Organisation<br>Belgium | Use as an analytical reagent<br>Potassium chromate is an important substance for scientific research and development, which is performed in the pharmaceutical industry and in routine analyses. It is actually not possible to replace potassium chromate in these applications.<br>Liquid potassium chromate formulations are used as analytical reagent, e.g. as volumetric solution or for the standardization of volumetric solutions and instruments in the pharmaceutical industry and ISO-certificated labs.<br>Potassium chromate formulations for standardization purposes and as analytical reagent are prescribed in the European Pharmacopoeia (Ph. Eur.), in the US Pharmacopoeia (USP), and in the ACS.<br>The usage of potassium chromate is still state of the art, no alternative methods are available. At the moment there is no evidence, that either the European or the US Pharmacopoeia is seeking for alternatives to potassium chromate formulations.<br>ISO-certified labs and pharmaceutical quality control labs in the EU are obliged by governmental organizations (e.g. FDA) to perform the calibration of UV/VIS photometer on a regular basis and therefore have the need to use potassium chromate formulations. |

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| | | | All formulations mentioned in the uses described above are used in the laboratory by industrial and professional users that are well-trained. The concentration used in these formulations is low (up to<br>0.5 % as a maximum), the volume needed for one analysis/calibration is in the range of volumes used in the laboratory.<br>According to our knowledge the majority of the potassium chromate formulations used for calibration purposes and as analytical reagents are disposed of in line with current legislation.<br>This reagent is used in the preparation of Potassium Chromate Solution R. This solution has specific uses in the identity tests for the 3% and 30% hydrogen peroxide monographs, the assay procedure for the chloral hydrate monograph, and in the determination of sodium chloride in the Sodium Lauryl Sulfate, Dextran 1 for Injection and Sodium Cetostearyl Sulfate monographs. Potassium Chromate Solution R is also used in the soluble chlorides test in the Magaldrate monograph.<br>Significance of the European Pharmacopoeia<br>The European Pharmacopoeia (Ph. Eur.) is prepared under the authority of the Council of Europe. The governments of Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, 'the former Yugoslav Republic of Macedonia', Turkey and the United Kingdom currently recognize the European Pharmacopoeia. Articles (drug substance or excipients) covered by a Ph. Eur. monograph must meet the requirements of the monograph, including any applicable general tests referenced by the monograph in order to be legally marketed or used in a marketed medicinal product.<br>In the light of the above considerations, EFPIA Recommends that Potassium Chromate be exempt from authorisation for any use in the research, development, manufacture or anlytical control of medicinal products and their ingredients and for any corresponding uses in relation to medical devices and diagnostic tests<br>This should cover the steps starting from manufacture of the substance (already exempted), filling into packages, preparation of formulations described in standards (DIN, EN, ISO and ASTM), Pharmacopoeias (Reag. Ph. Eur. and ACS) till the use as calibration standard for ICP and AAS. The use of these formulations for scientific R&D (< 1t/a) is already exempted.<br>The criteria for prioritization of substances for inclusion into Annex XIV are listed in<br>Art. 58 (3):<br>a) PBT or vPvB properties, or<br>b) wide dispersive use, or |

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| | | | c) high volumes.<br>None of these criteria applies to Potassium Chromate. As mentioned in the background document, the volume of Potassium Chromate regulated by the authorization in the EU is quite low and the uses of the substance are not considered as wide dispersive.<br>Nevertheless, we understand the need for the authorization of Potassium Chromate (regulatory effectiveness) to prevent the switch from other cobalt salts, which are fulfilling the criteria of Art. 58 (3), to Potassium Chromate for some uses. However, this should not lead to authorization for uses of Potassium Chromate which are not related to this regulatory effectiveness and which would not have been in focus of authorization based solely on the criteria of Art. 58 (3). |
| 1130 | 2011/09/13 18:21 | Agoria<br><br>Industry or trade association Belgium | We think that at least for hard chromium plating in appropriate installation a generic exemption should be given. We do see several arguments linked to this demand:<br>- The low to non-existing exposure in the workplace. The only possible exposure is within the eventual setting-up, maintenance and or intervention in the automatic line. This limits even further the exposure time period and workers can be well protected during these interventions<br>- The fact that the general public is not exposed at all given that the end product is not containing any chromium VI component, only a chrome metal plating,<br>- It remains difficult to find technically and economic viable substitution products or processes and there is a high potential of complete delocalization of the production out of Europe. This will have an important impact on the supply chain, including some major pressure for the closing of certain important production plants given the fact that this step is an important element in the added value of these production chains.<br>We also believe that for hardchromation the proposed substances are to be seen as intermediates as they are transformed during the production process. These are in general exempted from the authorization process (article 2 §8 of REACH). |

## IV - COMMENTS ON USES FOR WHICH REVIEW PERIODS SHOULD BE INCLUDED IN ANNEX XIV, INCLUDING REASONS FOR THAT:

| # | Date (Attachment provided) | Submitted by (name, Organisation/ MSCA) | Comment |
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| 598 | 2011/09/07 15:15 | Company Germany | 10 years, due to the fact that national and international normations most likely will not be changed in a shorter period of time. |
| 1596 | 2011/09/14 14:59<br><br>File attached Confidential | Company United Kingdom | The Aerospace and Defence industry operates very long life cycle products, many in excess of 40 years in service. The industry is heavily regulated and the introduction of new processes even when approved still takes a considerable amount of time. In addition these new processes are unlikely to be backwards compatible ie they cannot be used to repair or maintain products which are already in service (the original process will still be required).<br>Therefore identifying short review periods for Aerospace and defence industry critical uses of potassium dichromate will not be an efficient use of EHCA's resources. The recommendation is not to include review periods for these uses however if they must be included then they should be many years apart in order to reflect the complex nature of developing and obtaining approval for alternatives. |