

20 DECEMBER 2011

ANNEX V TO RESPONSES TO COMMENTS DOCUMENT (RCOM) ON ECHA'S DRAFT 3RD RECOMMENDATION FOR THE GROUP OF RECOMMENDED CHROMIUM (VI) COMPOUNDS - COMMENTS ON AMMONIUM DICHROMATE (EC NUMBER: 232-143-1)

THIS DOCUMENT PROVIDES THE COMMENTS RECEIVED ON AMMONIUM DICHROMATE 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
1736	2011/09/14 18:22 File attached Confidential	micrometal GmbH Company Germany	

1495	2011/09/14 12:14 File attached Confidential	Company Spain	<p>Ammonium dichromate (CAS 7789-09-5 EC 232-143-1) has been classified as</p> <ul style="list-style-type: none"> • Carcinogen category 2, R45 (May cause cancer) • Mutagen category 2, R46 (May cause heritable genetic damage) • Toxic to reproduction category 2, R60-61 (May impair fertility. May cause harm to the unborn child) <p>ITP, as a designer and manufacturer of Low Pressure Turbines for aeronautic engines, agrees with this classification and support the principle of prioritization based on classification of the substances in combination with the additional criteria of wide dispersive uses and high production volumes.</p>
585	2011/09/05 16:41 File attached Confidential	Company United Kingdom	<p>Ammonium dichromate (CAS 7789-09-5 EC 232-143-1) has been classified as</p> <p>Carcinogen category 2, R45 (May cause cancer) Mutagen category 2, R46 (May cause heritable genetic damage) Toxic for reproduction category 2, R60-61 (May impair fertility. May cause harm to the unborn child)</p> <p>&nbsp;</p> <p>Due to this classification, this substance was added to the candidate list for authorisation in June 2010. Manufacturers and developers of Gas Turbines agree with this classification.</p>

1844	2011/09/14 23:56	Company Germany	<p>Ammoniumdichromat ist bisher nur von einer Firma als transportiertes, isoliertes Intermediat registriert worden. Die importierten Mengen liegen im Bereich von 1-10t. Fast die gesamte importierte Jahresmenge wird als transportiertes, isoliertes Intermediat verwendet. Lediglich eine sehr kleine Menge (< 100kg) wird als Laborreagenz für die wissenschaftliche Forschung & Entwicklung und Analytik verwendet. Die Verwendung in diesem Bereich unterliegt den gesetzlichen Vorgaben der Gefahrstoffverordnung, bzw. anderen Vorschriften für den Umgang mit krebserzeugenden Gefahrstoffen, und wird nur von qualifiziertem Personal ausgeführt. Eine breite Exposition von Mensch und Umwelt ist somit ausgeschlossen. Alle Verwendungen finden unter kontrollierten Bedingungen statt.</p> <p>Aufgrund der geringen vermarkteten Menge und der oben beschriebenen kontrollierten Verwendungen besteht keine Notwendigkeit für eine Priorisierung des Stoffes gemäß den Kriterien von Art.57(3) REACH-VO für die Aufnahme in Anhang 14.</p> <p>Zur Vermeidung möglicher Einschränkungen der Verwendung dieses Stoffes im Bereich der wissenschaftlichen Forschung und Entwicklung sollte er nicht in Anhang 14 aufgenommen werden.</p>
933	2011/09/13 13:17	United Kingdom MemberState United Kingdom	<p>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.</p> <p>Chromium Trioxide Acids generated from Chromium Trioxide and there oligomers. Sodium Dichromate</p> <p>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.</p> <p>Ammonium Dichromate Sodium Chromate Potassium Dichromate Potassium Chromate</p>
928	2011/09/13 13:12	United Kingdom MemberState United Kingdom	<p>Based on the prioritisation criteria and the possibility of significant workplace exposure we agree with the proposal to recommend trichloroethylene for inclusion in Annex XIV.</p>

530	2011/08/17 13:41	MTU Aero Engines GmbH Company Germany	Die gefährlichen Eigenschaften der betroffenen Chromate sind uns als Luftfahrtunternehmen wohl bekannt. Es ist auch unbestritten, dass der Einsatz und die Verwendung dieser Stoffe nur unter sicheren Bedingungen möglich ist. Hier ist das Gesundheitsrisiko für die Betroffenen auf das notwendige Minimum zu reduzieren. Entsprechende Bestrebungen und Verpflichtungen zur Stoffminimierung und Substitution sind in Deutschland durch die nationale Gesetzgebung vorgegeben. An diesen Themen wird kontinuierlich gearbeitet. Ein gänzlicher Verzicht auf diese Stoffe und die damit verbundenen Verfahren ist aus heutiger Sicht erst mit der Validierung ungefährlcher Ersatzverfahren möglich. Die dort erzeugten Ergebnisse bedürfen dann noch die Anerkennung und Zulassung aller nationalen und internationalen Luftfahrtbehörden.
982	2011/09/13 14:50	AREVA Company France	Laboratory measurement 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.
499	2011/07/27 17:18	BEP Surfacing Technologies Limited Company United Kingdom	The use of these substances in our sector should not be subject to authorisation because: a) They are already subject to many different pieces of legislation b) Biological monitoring by the HSE has shown that median levels are equivalent to background levels i.e. no exposure c) Consumers are not exposed to the substances as they are converted to metallic chrome during processing d) Authorisation will not improve worker health & safety nor environmental protection e) Significant loss of manufacturing will occur because the substances will still be available for use outside of the EU
496	2011/07/27 15:53	Company United Kingdom	The use of these substances in the electroplating sector should not be subject to authorisation because: a) They are already subject to many different pieces of legislation b) Biological monitoring by the HSE has shown that median levels are equivalent to background levels i.e. no exposure. c) consumers are not exposed to the substances as they are converted to metallic to metallic chrome during processing. d) authorisation will not improve worker health and safety nor environmental protection. e) Significant loss of manufacturing will occur because the substances will still be available outside

			the EU.
1757	2011/09/14 18:56 File attached	SMS Siemag AG Company Germany	<p>To clarify specific points of discussion and make the arguments more understandable the study attached "Report on inclusion of chromium trioxide (CrO₃) in Annex XIV was carried out. For detailed arguments, evidences and citation please see the study attached. The results are summarized below.</p> <ol style="list-style-type: none"> 1. Occupational safety <ol style="list-style-type: none"> a. The quality of the data of the dossier published for consultation is not reproducible and unclear (For details see attachment). b. No risk in application of Chromic acid or Chromium trioxide for the end-consumer or industrial client. c. Safe handling of the solutions to minimize the risk for the co-workers for dermal or respiratory tract absorption. 2. Occupational diseases <p>According to the estimate made by the author in the annex XV report, approximately 440,000 employees work in the surface treatment industry in Europe. Of these approximately one-tenth work with chromium (VI); amounting to approx. 44,000 employees in the EU. In Germany, the metal refining industry employees approximately 45,000 people. Assuming that in Germany approx. one-tenth also work with chromium (VI), this means 4,500 employees for Germany. Above we have shown, that the cases of lung cancer involving workers working with chromium in plating plants averaged 1.4 cases per year during the last 10 years. For the 4,500 employees working with chromium (VI) this means the risk of contracting lung cancer is 0.00031 or 3.1 out of 10,000. By comparison the risk for the entire German population, of dying of lung cancer was 5.2 out of 10,000 in 2009. (For details see attachment).</p> 3. Alternative processes <ol style="list-style-type: none"> a. There are a variety of familiar alternatives for functional chromium plating using hexavalent electrolytes. These alternatives do not include one universal substitute process, capable of replacing hard chromium plating on a one to one basis (For details see attachment). b. If the functional hard chromium plating is to be replaced, it will be necessary to use

		<p>processes, which do not have the same technical or mechanical properties and, in terms of health, do not offer any improvement in employee protection, because these introduce familiar as well as less well researched safety hazards. Other alternatives, on the other hand, are considered relatively harmless in terms of hazardous substances, however, from a technical vantage point, can only be considered as a substitute for niche applications.</p> <p>4. Overall implications:</p> <p>a. The application of hard chromium plating in shows a high socio-economic benefits due to the functional properties in a wide range of products (For details see attachment).</p> <p>5. Summarized comments:</p> <ul style="list-style-type: none"> • It is difficult to see why the current justification and proportionality of the relevant provisions to handle Chromic acid and Chromium trioxid should need further approvals. National and European law already requires aspects of regulatory monitoring and control as well as to the increasing internationalization of requirements. Any additional configurable prioritization and approval of changes will only reproduce the current national requirements. • Furthermore, a separation in chromic acid and chromium trioxide is senseless from the chemical point of view. • Many decades provides a clear understanding of the safety and efficacy and show that on no account an endangering of the end-consumer is realistic. <p>6. Consequence:</p> <p>Taking these experiences into account an inclusion of the hard chromium plating from Chromic acid in Annex XIV of the REACh regulation should be avoided.</p> <p>At SMS Siemag the hard chromium plating of functional surfaces is applicatet in the following fields:</p> <ul style="list-style-type: none"> - manufacturing of hydraulic pistons for CVC and HGC-Systems (CVC = Continously Varaible Crown; HGC = Hydraulic Gap Setting) - repair procedures for core parts (parts with high value and/or long delivery times) e.g. in relation with an emergency breakdown of a customer plant. <p>Especially for repair procedures only the chromium plating process can reproducably produce the surface properties which are needed for rolling mill equipment. SMS Siemag is working together with renowned suppliers in Germany and is not possessing its own plating equipment.</p>
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866	2011/09/13 03:04	TriQuint Semiconductor, Inc. Company United States	<p>TriQuint does not use ammonium dichromate, and does not plan to ever use it. We do not have a stake in this consultation, other than the desire to ensure that the REACH requirements and processes are followed.</p> <p>Due to the low score for prioritization for this substance, it should not be added to Annex XIV. This substance scores a 1 on the prioritization criteria, and should not have been prioritized for inclusion in Annex XIV.</p> <p>The fact that a substance may be used in some new way in the future has not been a criteria in the past, and should not become one at this time. ECHA needs to decide on the rules for substance classifications and prioritizations and then stick to the rules. The current prioritization criteria were developed in the REACH regulation, and work very well.</p> <p>The fact that the substance is listed as an SVHC will be enough of a deterrent on future uses of the substance.</p>
1090	2011/09/13 17:42	Germany MemberState Germany	We support the ECHA proposal on prioritisation of ammonium dichromate.
1024	2011/09/13 16:13	Health and Environment Alliance International NGO Belgium	We support the inclusion of Ammonium dichromate to Annex XIV
962	2011/09/13 14:24	Sweden MemberState Sweden	We support the prioritisation of ammonium dichromate for inclusion in Annex XIV even though the scoring approach results in very low priority. As chromium (VI) compounds have partially the same uses and could be replaced by each other a grouping approach is warranted.

543	2011/08/24 13:45	WWF European Policy Office International NGO 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.
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II - TRANSITIONAL ARRANGEMENTS. COMMENTS ON THE PROPOSED DATES:

#	Date (Attachment provided)	Submitted by (name, Organisatio n/MSCA)	Comment
530	2011/08/17 13:41	MTU Aero Engines GmbH Company Germany	Aufgrund der komplexen Zulassungsverfahren in der Luftfahrtindustrie sehen wir die-se Fristen als zu kurz an und schlagen eine Verlängerung um bis zu 5 Jahren bzw. eine Verlängerung bis zum Vorliegen weiterer fundierter Daten und Untersuchungen vor. Ziel sollte es selbstverständlich sein, weiter zu versuchen diesen Stoff bzw. die eingesetzten Verfahren zu substituieren.

585	2011/09/05 16:41 File attached Confidential	Company United Kingdom	No comments.
543	2011/08/24 13:45	WWF European Policy Office International NGO 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.
962	2011/09/13 14:24	Sweden 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, Organisatio n/MSCA)	Comment
530	2011/08/17 13:41	MTU Aero Engines GmbH Company Germany	<p>Eine Ausnahme von der Zulassungspflicht für die Luftfahrtindustrie ist anzustreben. Um die Sicherheit im Bereich der Luftfahrt weiter aufrecht erhalten zu können, ist es zwingend erforderlich, galvanische Verfahren mit gefährlichen Stoffen zu betreiben. Ammoniumdichromat wird in der MTU Aero Engines GmbH zum Chromatieren von Flugtriebwerksbauteilen aus Magnesium eingesetzt. Dies geschieht in Deutschland (hier liegt eine sehr restriktive Anforderung der Chemikalien- und Umweltgesetzgebung vor) nach dem Stand der Technik. Der Schutz der Mitarbeiter ist jederzeit durch die technischen-, organisatorischen- und persönlichen Schutzmaßnahmen sichergestellt. Eine Einschränkung dieser Anwendung hätte zur Folge, dass die Sicherheit bestimmter Flugtriebwerkbauteile nicht mehr gewährleistet werden kann. Dem Anspruch der Luftfahrtindustrie, sichere Verkehrsmittel zu erstellen um damit die Sicherheit eines zukunftssträchtigen Verkehrsbereiches zu gewährleisten, ist nur mit besonderen, international festgeschriebenen Verfahren zu erfüllen. Demzufolge, um die Sicherheit der Bauteile weiter aufrecht erhalten zu können, ist damit zu rechnen, dass über die Verlagerung entsprechender Verfahren ins außereuropäische Ausland nachgedacht wird. Mit der potentiellen Verlagerung würden Teile von Hochtechnologie in Europa verloren gehen. Außerdem ist bekannt, dass in einigen außereuropäischen Ländern verschiedene Gefahrstoffe nicht als solche eingestuft sind. Durch Verlagerung von Produktion und Verfahren in diesen Ländern ist mit einer höheren Gefährdung der Umwelt und der Mitarbeiter zu rechnen.</p>

1844	2011/09/14 23:56	Company Germany	Im Falle einer Aufnahme in Anhang 14 sollte die Verwendung in der wissenschaftlichen Forschung und Entwicklung sowie Analytik ausgenommen werden.
1495	2011/09/14 12:14 File attached Confidential	Company Spain	<p>ITP, as a designer and manufacturer of Low Pressure Turbines for aeronautic engines, agrees with this classification and support the principle of prioritization based on classification of the substances in combination with the additional criteria of wide dispersive uses and high production volumes.</p> <p>With the basis of Article 58 (2) & 56 (1, 2, & 3) of REACH regulation and also the definition of the Article 3(23), ITP would request to the members to consider exemption from authorization requirement for the specific use of ammonium dichromate as a substance for Scientific Research & Development (SRD) of low pressure turbines.</p> <p>According to Article 58(2), "Uses or categories of uses may be exempted from the authorization requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form" And the article 56 (1, 2, & 3) states "1.- A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless: 2.- A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorization granted to an actor up his supply chain for that use. 3.- Paragraphs 1 and 2 shall not apply to the use of substances in scientific research and development. Annex XIV shall specify if paragraphs 1 and 2 apply to product and process orientated research and development as well as the maximum quantity exempted."</p>

			<p>And also according to definition of the article 3 (23) “Scientific research and development: means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year” The request of exemption from the authorization requirement for the substance ammonium dichromate is based on the fact that the risk to human health and the environment associated with use is very low given the conditions in ITP. These conditions are explained in more detail in the attached document, which contains information on the following topics:</p> <ol style="list-style-type: none"> 1.- Exclusive use of ammonium dichromate in Scientific Research & Development for low pressure turbines 2.- Controlled conditions of use. 3.- Use of very low quantity of ammonium dichromate 4.- Ammonium dichromate in the workplace environment <p>We have attached the following documents for your consideration:</p> <ul style="list-style-type: none"> - Our letter explaining the reasons of this request and briefly the conditions of the use of ammonium dichromate in our company. - A confidential explanation of the use of ammonium dichromate, containing the following information <ol style="list-style-type: none"> 1.- Exclusive use of ammonium dichromate in Scientific Research & Development for low pressure turbines 2.- Controlled conditions of use. 3.- Use of very low quantity of ammonium dichromate 4.- Ammonium dichromate in the workplace environment
1736	2011/09/14 18:22 File attached Confidential	micrometal GmbH Company Germany	<p>MICROMETAL is a user of ammonium dichromate. MICROMETAL applies for an exemption from inclusion in ANNEX XIV. Introduction of the company: MICROMETAL is an etching company with 40 employees. MICROMETAL processes metal foils. The products are used worldwide, among others, in the automotive industry, the chemical industry, the medical technology and the environmental technology. The manufacturing plant is working around-the-clock and highly automated. The shift workers are in the plant for control and monitoring purposes only. MICROMETALs specific use of ammonium dichromate</p>

			<p>Ammonium dicromate is used as a photosensitizer. The concentration is less than 1% in an aqueous system.</p> <p>Ammonium dicromate as photosensitizer is of vital significance for MICROMETAL. As ingredient of MICROMETAL's photoresist it allows MICROMETAL to reach the claimed accuracy of the products. This was not possible with other photosensitizers yet. Trials with less critical photosensitizers were done, but tests under production conditions showed insufficient results.</p> <p>Justification for exemption from inclusion in ANNEX XIV for using ADC as a photosensitizer in water based photoresist-systems:</p> <ol style="list-style-type: none"> 1. Draft of ECHA-Background-Document for ADC / 3.1: There is a concern that ADC could be used to replace other hexavalent chromium compounds with similar hazardous profile and similar uses. This does not apply to MICROMETAL, who uses ADC for many years in above mentioned way. 2. ADC is a cmr-substance. In Germany use of cmr-substances is regulated by "Gefahrstoff-Verordnung" (Issue 28.07.2011, §10) . Application of ADC as used at MICROMETAL is not forbidden in Germany. 3. Releases and exposure to workers are controlled. This is achieved by factors listed below: <ul style="list-style-type: none"> • Formulation of ADC and kind of use of ADC prevent / minimize release and thus exposure to workers. • Duration while workers are handling ADC is very short: 1 worker, 1,5h/month • Duration of workers staying in those areas of production-line where ADC-solution is processed takes about 10% of working-time (Production-line is operating highly automatically) • Duration of the worker staying in the waste-water-treatment-plant is less than 1h/d. (Cr-VI-concentration in waste-water is lower than 0,002%) 4. Releases and exposure to environment are controlled: <ul style="list-style-type: none"> • ADC is no part of finished goods • Release to environment is prevented by complete collection and treatment of ADC within production-building followed by disposal of treated chromium-containing waste. 5. Consumption of ADC is very small: Less than 1t/a <p>Further information to items 3 and 4 see attachment.</p>
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585	2011/09/05 16:41 File attached Confidential	Company United Kingdom	<p>The manufacturers of gas turbines for a variety of applications would like to draw the attention of the EC, ECHA and the Competent Authorities for the Member States to one particular application of ammonium dichromate which has extremely low volumes of use, results in very few individuals being exposed across the industry, in an easily controlled environment, which does not have wide dispersive use, and is currently vital for the development, testing, and improvement of new, safe and efficient gas turbines across all industry sectors.</p> <p>&nbsp;</p> <p>This use is specific to Scientific Research & Development for gas turbines and engines.</p> <p>&nbsp;</p> <p>We have noted that under Article 56 (3) of REACH there is an opportunity for you to consider uses that have a very low risk for possible exemption from the authorisation requirement. We would ask that this use of ammonium dichromate be considered for exemption.</p> <p>Article 56 states: "General provisions A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV...</p> <p>2. A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.</p> <p>3. Paragraphs 1 and 2 shall not apply to the use of substances in scientific research and development. Annex XIV shall specify if paragraphs 1 and 2 apply to product and process orientated research and development as well as the maximum quantity exempted."</p> <p>The total consumption of ammonium dichromate in the gas turbine and power-systems industry in Europe for this particular use is probably less than 10kg per annum. The consumption of the company submitting these comments is on average, less than 300 gr used per annum, and the consumption has never exceeded 500 gr per annum.</p> <p>&nbsp;</p> <p>We have attached the following documents for your consideration: Our letter explaining the technical uses of ammonium dichromate including their use to prove the safety of the product (Attachment 1). A commercially confidential step-by-step explanation of the use of ammonium dichromate, from receipt to final disposal, with relevant operational conditions and risk management measures (Attachment 2). Commercially confidential workplace exposure monitoring report for manufacture and use at our facility (Attachment 3).</p>
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			Commercially confidential risk assessment for the various processes at our facility (Attachment 4). Materials safety data sheets for P354 (Attachments 5 to 7)
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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
585	2011/09/05 16:41 File attached Confidential	Company United Kingdom	No comments.
1024	2011/09/13 16:13	Health and Environment Alliance International NGO Belgium	The review period should be short, for example 5 years.

530	2011/08/17 13:41	MTU Aero Engines GmbH Company Germany	Wir sind der Überzeugung, dass in einem Zeitrahmen von 5 – 7 Jahren, bei entsprechender Datenlage, Zulassungen neu bewertet werden könnten.
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