

# ASD-EUROSPACE The Space group in ASD

# SPACE SECTOR CONTRIBUTION TO THE EC REACH REVIEW 2017 – POSITION PAPER

This is the joint contribution to the European Commission (EC) REACH review 2017 ( $REFIT^{1}$  evaluation) of the European Space Industry - represented by ASD-Eurospace – with the support of European and national space agencies.<sup>2</sup> Furthermore, reference is made to the contribution by ASD of 24 January 2017 to the same consultation; it is fully supported by the space industry.

## **1. INTRODUCTION**

The REACH requirements impact the European space sector to a great extent, both from a regulatory compliance and commercial perspective. The processes for Registration and in particular Authorisation of Substances of Very High Concern (SVHC), which aim at their substitution with suitable alternatives, pose continuous challenges or even risks that have to be actively monitored and mitigated by the space industry to avoid costly production and supply chain disruptions in order to secure the reliable continuation of space activities and the EU's independent access to space as a key element of the EU's space policy<sup>3</sup> in an increasingly competitive environment globally. The strict communication requirements of REACH Article 33<sup>4</sup> pose a further specific challenge for the space industry as manufacturers of highly complex launcher and space systems (space vehicles<sup>5</sup>).

The objective of the document is to

- Outline key REACH relevant features of the space sector (Section 2);
- Highlight key sector concerns with regard to REACH and return on experience (Section 3);
- Provide recommendations for REACH implementation improvement (Section 4).

<sup>&</sup>lt;sup>1</sup> Regulatory Fitness and Performance Programme of the EC, covering five compulsory evaluation criteria: Effectiveness, Efficiency, Relevance, Coherence and EU Added Value, including examining the potential to improve the way in which REACH delivers on its objectives and the potential for burden reduction and simplification.

The contribution has been prepared in the frame of the Materials and Processes Technology Board of the European Space Components Coordination (ESCC MPTB). The ESCC MPTB is a partnership between the European Space Agency (ESA), national space agencies, and space industry represented by Eurospace, chaired at present by ESA. Current participants from Eurospace include: Airbus Defence & Space, Airbus Safran Launchers, Avio, OHB, RUAG, TESAT and Thales Alenia Space. Participating national space agencies are: Agenzia Spaziale Italiana (ASI), Centre National d'Etudes Spatiales (CNES) and Deutsches Zentrum für Luft- und Raumfahrt e.V. (DLR). Other participants are MAP, a manufacturer of mixtures, and ReachLaw, a consultancy supporting the group on REACH and other chemicals regulations.

https://ec.europa.eu/growth/sectors/space\_en. In its "Space Strategy for Europe" of 26 October 2016 the European Commission proposes a number of actions to maintain Europe's autonomous access to space.

As recently confirmed by the judgment of the Court of Justice of the European Union (Case C-106/14), see <a href="http://curia.europa.eu/juris/document/document.jsf?text=&docid=167286&pageIndex=0&doclang=EN&mode=Ist&dir=&docd=11240">http://curia.europa.eu/juris/document/document.jsf?text=&docid=167286&pageIndex=0&doclang=EN&mode=Ist&dir=&docd=11240</a>

For the purpose of this Position Paper the term space vehicle refers to space launch vehicles (launchers) and spacecraft (e.g., satellite systems, probes). Space vehicles are procured by governments, public institutions (military and civil) and commercial entities in Europe and worldwide.

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A specific (non-industrial) concern with regard to institutional customers is presented in a dedicated <u>Annex</u> to this document: REACH status of governmental agencies.

# 2. REACH RELEVANT FEATURES OF THE SPACE SECTOR

## HIGH-END NICHE SECTOR

The space industry operates with very small production runs, demanding qualification requirements and very long lifecycles from design and production to exploitation phases (long length programmes).

The sector is of high strategic importance and a driving force for a lot of public good. European public institutions (such as ESA and the  $EC^{6}$ ) play a key role in the space sector and their involvement is essential to sustain the space economy. They are the largest part of the sector's customer base (sales to ESA represent 35% of total European space sector sales). Long investments from EU governments are supporting the EU's access to space.

Stringent safety and reliability requirements need to be met. Space products operate under extreme environmental conditions and no failure is permitted. End-customers therefore demand technology maturity,<sup>7</sup> but also heritage<sup>8</sup> and experience from their suppliers. Long-term decisions on the design and technologies – and hence substances – used for space programmes are made early on in their development phase, with later changes being impossible or very difficult as illustrated hereafter:

- For *launchers*, the design is frozen when the development contract is signed. When the design is qualified, no system requalification is planned<sup>9</sup> and production has to be sustainable until the end of the programme. As an example, aluminium alloy components of the Ariane series of launchers (Ariane 5 and its developments) and VEGA have been treated with chromium trioxide since 1979 and the family of Ariane launchers has completed more than 200 successful launches.
- For satellites and other spacecraft, manufacturers must demonstrate successful operation in orbit, including performance over many years with no opportunity for repair and maintenance. A platform design can be exploited from 15-20 years without significant modifications in its architecture. Any new designs and changes to heritage designs require extensive qualification testing at all levels of the assembly.

#### INFO BOX: THE EUROPEAN UNION'S GALILEO SATELLITE SYSTEM

Heritage programmes are a key concern for the space vehicles manufacturers and users. An example of this kind of programme is the European Union's Galileo satellite system. This is a constellation of at least 30 satellites; the first satellites being launched in 2011. The design and production is fixed to ensure operability of the entire constellation as a whole. The initial design and launch of the first phase of satellites was before the sunset date of chromium trioxide, with the final satellites to be placed into orbit in 2020, after the sunset date.

See <u>COM(2013) 108 final – "EU Space Industrial Policy"</u> (28 February 2013).

The concept of Technology Readiness Levels is broadly used:

https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014\_2015/annexes/h2020-wp1415-annex-g-trl\_en.pdf.

<sup>&</sup>lt;sup>•</sup> Heritage is hugely important within the space industry. It involves using the experience of processes, parts and technologies from previous missions to give credibility and confidence in their performance for future missions. It is one of the key drivers behind, for example, the continued use of Cr(VI) coating on aluminium alloys in space vehicles, for both commercial and institutional customers.

Some requalification for obsolescence treatment may be possible, but it is costly and time-consuming with respect to the lifecycle of the launcher.



#### COMPLEX SUPPLY CHAINS

The supply chains are very complex and always international with many contractor levels and a large number of players.<sup>47</sup> The main actors in the space sector are often active along entire manufacturing value chains. Since the early 2000s many small manufacturing companies have emerged within the space sector, in parallel to the larger actors.

The supply chains are different for launchers, satellites and other spacecraft:

- For *launchers* the system configuration is fixed at the qualification stage and must remain identical for the whole lifecycle of launcher production.<sup>11</sup> This means that the supply chain is fixed in that every actor can be identified. It also means that heritage is very important.
- Satellites and other spacecraft, on the other hand, are produced according to specifications of system providers and are therefore not fixed. Some spacecraft are highly standardised while, at the other end, scientific satellites are highly customised. In between, telecommunication satellites have a standard platform but a customised payload.

#### LOW VOLUME USE OF CHEMICALS

Substances and mixtures are only used in the space industry in very low volumes, comparing to other sectors. Such low volumes present a further challenge in finding a viable alternative as chemical consumption by the space industry is dwarfed when compared with e.g. the aviation industry (space represents about 2 % of the volume of chromium trioxide used when compared to aviation).

#### DEPENDENCE ON A PLETHORA OF SUBSTANCES - IN A PLETHORA OF SYSTEMS

The manufacturing of space hardware depends on a plethora of substances regulated under REACH, including numerous substances targeted by harmonised classification (CLP), Risk Management Option Analysis (RMOA), the REACH candidate list and Annex XIV. Important examples (not exhaustive) include: beryllium, boric acid, Cr(VI), gallium arsenide, hydrazine, lead compounds, many solvents. The following info box "SVHC uses in space hardware" provides a non-exhaustive overview of the various sub-systems, where substances with SHVC properties are currently required.

#### INFO BOX: SVHC USES IN SPACE HARDWARE

Launchers: SVHCs are currently employed in sub-systems such as: propulsion; structures; and various mechanisms. Components in these sub-systems include stage structures; tanks; propellant tanks; pressure tanks; the fairing; payload adapters; liquid propulsion systems; storable liquid engines; cryogenic liquid engines; hydrocarbon liquid engines; solid propulsion motors; reaction and attitude control systems; pyrotechnics; and electronic components and assembly technologies.

Spacecraft: SVHCs are currently employed in sub-systems such as: attitude and orbit control; guidance, navigation and control; various mechanisms; on-board data management; optical communication; payloads; power generation; propulsion; RF/Microwave communication; structures; thermal control; and electronic components and assembly technologies.

Example: For space hardware surface treatment the space prime contractors typically use subcontractors to carry out all or parts of the surface treatment, in addition to in-house activities; in many cases those surface treatments are subcontracted by the first subcontractor. These subcontractors are often SMEs serving many companies in several industries.

Requalification of a supplier might be possible in specific cases of disruption of production due to closure/bankruptcy of the supplier, but it is costly and time consuming with respect to the lifecycle of the launcher.

## 3. KEY ISSUES WITH REGARD TO REACH AND RETURN ON EXPERIENCE

#### OBSOLESCENCE RISKS AND THEIR MAGNITUDE

For the European Space Industry as a very small volume user and thus typical niche customer for chemicals formulators and distributors, the market realities may lead to significant commercial obsolescence risks over and above the REACH regulatory demands. The latter are themselves already challenging to manage for the sector as end user of chemicals for the manufacture of highly complex systems for space activities, following often long and complex supply chains. Stakeholder communication (supply chain, authorities, associations, etc.) is pivotal for the success of sustainable supply.

In the context of REACH an obsolescence risk in the space industry can be defined as any possibility of impairment of quality and reliability or even loss of critical technologies for qualified materials and processes, which is induced by a chemical's unavailability or substitution threat. REACH poses two major forms of obsolescence risks for space activities:

- the regulatory obsolescence risk, mainly due to the legal ban for non-registered or non-authorised chemicals and their uses, respectively;
- the commercial obsolescence risk, for example when suppliers change or discontinue products used by the space sector and other, larger, sectors, when those larger sectors stop using the product; and this in spite of the high potential for REACH authorisation for the space sector.

In terms of magnitude, ca. 8% of the materials used in the space industry may be affected in the mid-term, and possibly 20% in the long-term, based on analysis of the REACH candidate list for authorisation and relevant precursor lists.<sup>12</sup> These high numbers show the significant potential impact of the REACH chemicals regulation on the space sector.

#### INFO BOX: OBSOLESCENCE RISK MANAGEMENT THROUGH THE ESCC MPTB

The magnitude of the risks and the smallness of the sector have prompted concerned stakeholders to enter into a European-wide coordination, realised through the ESCC MPTB. A large part of resources are dedicated to obsolescence risk management in relation to REACH. The MPTB allows early identification and proactive coordination of proper mitigation of obsolescence risks, including collaborative R&D partially funded by the Space Agencies. Furthermore, space sector interests are pursued by and co-ordinated with Eurospace and the ASD <sup>13</sup> REACH Implementation Working Group (RIWG). For most critical chemicals and related space applications presenting a high obsolescence risk with a specific need for joint regulatory mitigating action, the ESCC MPTB has initiated dedicated industry task forces under co-ordination of Eurospace, the European Space Industry trade association: Hydrazine Task Force (HTF) and Space Chromate Task Force (STF).<sup>14</sup>

A specific challenge arising from the lack of visibility in the complex upstream supply chains is the hidden obsolescence risk for substances used as precursors (intermediates), used in mixtures (but not identified in the safety data sheet) or in manufacturing processes, as they cannot be seen from the safety data sheet. Therefore it may be impossible at the end user level to detect important changes which may affect product quality and performance level.

Furthermore, there is a concern that the obsolescence will be further increased if substances are not registered by the final 2018 deadline and in case further SVHCs which are broadly used in the complex supply chains leading to the space sector are included in candidate list and Annex XIV.

<sup>&</sup>lt;sup>12</sup> This corresponds to about 150 materials used for launcher and spacecraft applications that actually or potentially affected in the mid-term and about 360 materials possibly affected in the long term, based on a preliminary assessment in the frame of the ESCC MPTB. In REACH terms the materials assessed comprise mainly mixtures (e.g. adhesives, coatings and paints), but also articles (e.g. composite materials and polymer films) and some clearly defined substances (e.g. hydrazine).

AeroSpace and Defence Industries Association of Europe (ASD).

<sup>&</sup>lt;sup>4</sup> See further below.



#### PREDICTABILITY WITH REGARD TO SVHC REGULATION

In spite of the EC's SVHC Roadmap to 2020, the ECHA PACT/RMOA list and overall efforts made by the EC, ECHA and Member State REACH Competent Authorities to streamline the different REACH processes for substances of concern (i.e. authorisation, evaluation, restrictions), the unpredictability whether, when and in which process a given substance will be further regulated under REACH, presents a significant challenge for the space sector when having to decide about the right course of action. The unrestricted possibility of further RMOAs by other Member States for the same substance after conclusion of the initial RMOA (e.g. to address another concern of the substance) creates additional uncertainties. The launching of R&D activities for substitution, followed by re-qualification and industrialisation (if a suitable alternative is found), has huge resource implications, and therefore requires a clear signal by the regulators whether or not the substance currently used as well as possible alternative substances will be banned in the foreseeable future. Today however, it is not always clear whether an SVHC will be included in the candidate list, and whether a candidate list substance will be included in the authorisation list. It may also be that a restriction is deemed as sufficient to manage the risk to human health or the environment, and industrial use may continue within the defined conditions / derogations. It might therefore be equally important to have a clear signal in case a substance will further be allowed for industrial uses.

#### REPLACEMENT OF SVHC

Significant substitution R&D activities are already on-going at industry, national, European and international levels for many critical SVHC substances, whether they are included in Annex XIV (e.g. Cr(VI)<sup>15</sup>) or not (e.g. hydrazine<sup>16</sup>). Replacement of SVHCs in the space sector is a lengthy and costly process. The challenge is further increased if substitution is envisaged within an existing space programme, because of the need for investment in the redesign by the space industry and European governments; and also the requirement for heritage by commercial and institutional customers.

Substitution costs for space industry for full replacement (if suitable alternatives become available for all applications) including R&D, testing, qualification, and industrialisation, have not yet been globally measured, and they depend on complexity and degree of system level impact. Yet, it can be clearly said that these costs are far higher than the direct REACH authorisation application costs.

Furthermore space companies may have to do substitution R&D for SVHCs to the detriment of other R&D activities. Thus, limited budgets have to be used to finance substitution R&D (i.e. to comply with REACH), while being at the same time diverted from innovative R&D to make better performing, cost effective and competitive products.

The value of joining forces to achieve substitution has been recognised in the space sector for many years: The ESCC MPTB has the reduction of programmatic risks and costs by early replacement, including use of alternatives, requalification or possibly new developments amongst its tasks.

#### SHORT ANNEX XIV SUNSET DATES

According to current practice the Annex XIV sunset dates are set at ca. 3 years after Annex XIV inclusion, and latest application dates 1,5 years before the sunset date. The main rationale for setting those dates is to give industry just enough time to prepare an application for authorisation (AfA) while taking account of ECHA's capacity to process those applications. But the current practice does not consider

- use-specific product lifecycles (e.g. in the space sector: the duration of specific programmes);
- the time needed to achieve substitution and thus avoiding the need for authorisation.

<sup>&</sup>lt;sup>15</sup> For example the joint ESA/NASA test campaign for the replacement of Alodine 1200 containing chromium trioxide.

<sup>&</sup>lt;sup>1</sup> ESA, national space agencies and the European Space Industry have been working on alternatives to hydrazine for launchers and spacecraft for over 15 years. ESA has ongoing and planned R&D activities under the CleanSpace and THAG Roadmap.

<sup>&</sup>lt;sup>1</sup> In practice, substitution activities may have been enhanced already earlier, e.g. following candidate list inclusion.

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Substitution in the space sector is typically a lengthy process and the programme duration may span over several decades. It depends on authorisation under short Annex XIV timelines and the need to run the double effort of continueduse applications and replacement efforts. Hence the authorisation impact is increased for high reliability sectors and low volume users such as space. Thus, short Annex XIV timelines as well as subsequent authorisation review periods not covering the full time needed for substitution – and hence more likely to require authorisation renewals – tend to affect the space sector disproportionately.

#### INFO BOX: LAUNCHER LIFECYCLES

Development cycles for a new launcher system are between 5 and 10 years, depending on the programme. These long development programmes lead to a standardised launcher configuration. When investing billions of Euros into a launcher it is expected that the operational life time will be as long as possible torecover development costs. Normally, the operational/exploitation time is about 30 years, whereas some sub-systems within launchers, e.g. engines, could have a longer lifetime for application in future launchers programmes when reused as is or with some adaptations.

Within a fixed configuration the replacement of any sub-assembly or equipment require the requalification of this subassembly and some of them can require the requalification of the launcher and of the supply chain.

#### AUTHORISATION APPLICATION CHALLENGES: CASE CHROMATES

Given the political nature and goals of space programme development and the substantial investments required by EU governments, and indeed the EU itself, to support the EU's independent access to space, on top of the strict type approval, standards and heritage required by the industry, the authorisation process is often seen as an inadequate risk management option for space specific uses.

Companies in the space sector incur a double penalty: They have been carrying out a huge amount of work to substitute chromates in some parts when possible and they had to apply for or support upstream authorisation where substitution by the sunset date could not be ensured. The space industry has been strongly impacted by the authorisation requirement for chromates. The Space Chromate Task Force ("STF", created 2013) has developed joint inputs to support the upstream authorisation for chromium trioxide required as component for surface treatment formulations.<sup>18</sup>

Indeed, the continued use-case as such could be made with strong arguments for space applications where replacement by the sunset date is not technically or economically feasible. Very significant assets are at stake, as shown for the example of chromium trioxide with upcoming "sunset date" of 21 September 2017: Economic losses in case of loss of manufacturing capability, as well as the impact on the local business environments, could be 2.6 B€ annually until a solution is found.<sup>19</sup>

However, there have been a number of serious challenges for the space industry with regard to chromate authorisation, which are due to its position as a small volume niche user:

- The space sector has to rely on upstream applications for authorisation to cover its complex supply chains and high number of downstream users (DU); including many SME surface treatment shops serving customers in several industries. However, the focus of such upstream applications has been on larger industry sectors, as they represent the main supplier business. Therefore the strong space case tends to be "diluted" among other sectors' uses.
- Restrictive authorisation conditions for such upstream applications (e.g. aiming at exposure reduction or improvement of risk management measures) could make it very difficult for downstream users (especially SMEs) in supply chains leading to the space industry to maintain the use.
- For broadly used substances such as chromium trioxide the space industry critically depends on upstream authorisations. To manage the risk of such upstream authorisations foreseeing too short review periods and

<sup>&</sup>lt;sup>18</sup> See <u>STF Comments on the CTAC(Sub) application for authorisation in public consultation</u>.

See previous footnote.



strict authorisation conditions, some space companies had to engage in multiple authorisation application efforts with corresponding cost implications (~0.5 M€). As an example, space companies participating in CTAC and CCST have also subsequently joined STF (which supported the CTAC application with an own technical comment, see above; a possible future application using STF deliverables e.g. after expiry of initial review periods may be necessary).

- There is limited interest of the upstream formulator to support a space-specific authorisation application, because space only represents a small part of the formulator's total business. Securing the continuation of supply of required surface treatment formulations requires a constant effort for the space industry to engage with their upstream suppliers and get their commitments to sustain the supply of SVHC-based systems.
- Only for very specific uses a DU-level AfA is viable. Currently there is merely one DU AfA from the space sector.<sup>20</sup> According to the AfA the total monetised impacts of the non-use scenario are a cost of approx. EUR 290 million during the requested review period, while the health impacts on workers and the general population due to the use of chromium trioxide by the applicant ranged from EUR 15 to 25. This equates to a ratio of 1 : 11,600,000, raising the question why such a clear use case has to go through the same extensive authorisation process like a broad upstream application covering hundreds of downstream users and several thousands of tonnes (the total volume for the AfA in question is 0.83 tonnes/year).<sup>21</sup>

## EXEMPTIONS FROM AUTHORISATION: CASE HYDRAZINE

Based on the outcome of an in-depth technico-legal analysis the Hydrazine Task Force ("HTF", created 2011) has jointly developed a Position Paper<sup>22</sup> to confirm an exemption from REACH authorisation for mission-critical space applications as fuel, mainly based on REACH Article 56(4)(d) ("use as fuels in closed systems"). Since the exemption clause has not been applied before and the terms are not further defined in REACH, ASD-Eurospace has presented the Position Paper to the European Commission in October 2012 in order to obtain a legal clarification.<sup>23</sup>

The case highlights well the persisting challenges to confirm general exemptions from authorisation based on the REACH legal text with the authorities (absence of a formal exemption granting process), where a substance is included in the candidate list for authorisation. Industry needs certainty about the regulatory treatment of candidate list substances and their uses in order to be able to make the right strategy decisions. This is especially relevant for taking correct design decision during early phases of long-term programmes such as launchers and satellite platforms.

## DIFFICULTIES TO COMPLY WITH REACH ARTICLE 33

As producers of highly complex hardware (launchers, satellites, etc.), which may be composed of hundreds of thousands or even millions of component articles, the space industry is strongly impacted by the duty to communicate information on substances in articles as set out in REACH Article 33, raising questions of proportionality. Furthermore, 10 years after the adoption of REACH, including Article 33, the requirements to comply with this provision are still not sufficiently clear. It is understood that the new ECHA Guidance for Substances in Articles to be issued in 2017 should clarify the situation.

For the surface preparation of aluminium alloy cryogenic tanks of the Ariane 5 launcher, see <a href="https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/15317/term">https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/15317/term</a>.

The combined tonnage used of chromium trioxide for the 8 companies of the STF is ~2-3 tonnes/year. This figure is estimated based on the use in chromic (chemical) conversion coatings by the space companies themselves and their sub-contractors.

<sup>&</sup>lt;u>http://www.eurospace.org/Data/Sites/1/pdf/positionpapers/hydrazinereachpositionpaper\_final\_14june2012.pdf.</u>

<sup>&</sup>lt;sup>2</sup> See also <u>parliamentary question (E-003827-2016) "Impact of REACH legislation on the European space industry"</u> (9 May 2016) and <u>Answer given by</u> <u>Ms Bieńkowska on behalf of the Commission</u> (28 July 2016). In the meantime ECHA has clarified that the exemption in REACH Article 56 (4)(d) also covers the lifecycle steps preceding the end-use as a fuel, see Q&A ID 1028, available at <u>http://www.echa.europa.eu/web/guest/support/qas-</u> <u>support/qas</u>.

## 4. RECOMMENDATIONS

Regulators should consider the vital needs for predictability, legal certainty and specifics of the space sector described in this document when making decisions affecting the space industry, notably in the frame of RMOA, REACH authorisation listing and when determining the review period for authorisation applications covering the space sector. Thus the aims to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation (REACH Article 1(1)) on the one hand and to safeguard the EU's independent access to space and other elements of the EU space policy on the other hand can be achieved.

In particular, the following recommendations can be made, based on the key issues raised above:

## MORE TIME FOR INNOVATIVE SUBSTITUTION

The constraints to achieve substitution (i.e. replacement with at least the same performance) in high reliability sectors such as space should be more considered before introducing regulatory measures (especially candidate list and Annex XIV), but also when determining phase-out timelines. The REACH Regulation has the required flexibility for this. Relevant provisions introduced by the REACH legislator should be used. For example, REACH Article 58(1)(c) allows the setting of use-specific sunset dates according to the *"production cycle specified for that use"*. This would contribute to the avoidance of unnecessary spending for authorisation and to the achievement of innovation, i.e. the generation of more competitive products.

## EU LEVEL FUNDING FOR SUBSTITUTION R&D

To mitigate the possible negative impact on innovative R&D and hence competitiveness and enhance substitution of SVHCs, dedicated EU level funding for REACH-related substitution R&D should be made available, e.g. under Horizon 2020 / its follow-up programme. Ideally, such funding would start before the Annex XIV inclusion, e.g. in connection with inclusion in the candidate list, or even earlier.<sup>24</sup>

## HARMONISED AND FORWARD-LOOKING RISK MANAGEMENT OPTION ANALYSIS

RMOA should be conducted in a more harmonised and predictable manner, according to defined processes and criteria. Before concluding on candidate list and Annex XIV as a "blanket" risk management instrument covering all non-exempted uses of a given substance, there should be a general assessment of the sectors affected, expected market responses in case of candidate list inclusion and the availability of alternatives for critical uses. To this end, sector stakeholders should be invited to provide relevant input (which is normally not included in the registration dossier). Non-REACH measures should also be explored, such as the sufficiency of EU OSH legislation (e.g. EU-wide binding Occupational Exposure Limits). The status of an SVHC substance or its precursor as a Critical Raw Material (CRM) according to the related EC CRM policy should also be considered when deciding on the appropriate Risk Management Option (e.g. beryllium, borates, cobalt).

## REGULATORY PREDICTABILITY FOR CRITICAL SUBSTANCES

There are a number of strategic substances with SHVC properties for high reliability sectors such as space, which could be prioritised for authorisation in the future.<sup>25</sup> These include for example (non-exhaustive): beryllium, bisphenol A, boric acid, cadmium, gallium arsenide, hydrazine, lead and its compounds. Predictability about the regulatory fate of these substances and the issues affecting it can be enhanced, including through:

- Completion of authority RMOAs / related prior requests to industry sectors;
- More substance-level communication by the EC, ECHA and MSCAs;

<sup>&</sup>lt;sup>2</sup> E.g. when an RMOA concludes on identification as SVHC and authorisation as suitable follow-up or substitution is already mandatory based on other applicable legal requirements, e.g. EU OSH legislation.

See already above in Section 3 "Obsolescence risks and their magnitude" with figures of materials for space systems actually or potentially affected.



- Dedicated IT tools that allow the automated tracking of substances of interest in regulatory processes, taking into account their dynamic nature and interconnections;<sup>26</sup>
- Legal clarity on the applicability of exemption clauses (example of hydrazine).

## AUTHORISATION: STREAMLINING AND SIMPLIFICATION

The space sector supports the EC's efforts to simplify authorisation for substances used in low volumes and legacy spare parts. Reference is made to the contribution by ASD-Eurospace in the EC public consultation on REACH Authorisation (29 April 2016). It is hoped that the rules will be in force before the next Annex XIV update takes effect. The work of the AfA Task Force of the EC, ECHA and MSCAs on the identification of further specific cases for simplified authorisation should be continued, especially where they facilitate authorisation for SMEs and for uses with specific characteristics, such as minimal expected health impacts.

Reference values for Annex XIV substances, importantly dose-response relationships for non-threshold substances, should be published by the ECHA Risk Assessment Committee by the time of Annex XIV inclusion, if not earlier, in order to support the most efficient preparation of applications for authorisation and a more predictable RAC opinion-making.

## SUBSTANCES IN COMPLEX ARTICLES: WORKABLE APPROACH

10 years after the adoption of REACH including Article 33 the requirements to comply with this provision are still not sufficiently clear. This applies even more to complex articles such as space hardware. Two recommendations are made:

- Within the existing framework: Relevant and practical ECHA guidance for complex articles: The ongoing update of the ECHA Guidance for Substances in Articles is expected to have a significant impact in terms of setting the enforcement boundaries and helping industry to comply with the provision given the complex international supply chains. Ideally the updated guidance would strike a proper balance of providing legal certainty on the one hand and allowing for the adoption of more specific guidelines by industry sectors on the other hand, in order to take into account the peculiarities associated with different types of complex articles, supply chains, communication needs, etc.
- Beyond the existing framework: Review of REACH Article 33: More generally, a review is recommended whether the REACH Regulation is indeed the right instrument to ensure the delivery of safe use information on hazardous substances in articles, and even more in very complex ones. In this respect it should be noted that the Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) foresees an exclusion for *"equipment designed to be sent into space"* (RoHS Article 2(4)(b)), whereas REACH Article 33 does not foresee an exemption of any kind / distinction depending on the complexity.

## MORE ATTENTION TO THE SPECIFIC ISSUES OF HIGH-END NICHE SECTORS

Generally for the implementation of REACH, it is recommended that regulators pay more attention to the specific issues of high reliability sectors such as the Space Sector (magnitude of the REACH-related obsolescence risk, dependence on complex supply chains, substitution constraints, strategic importance for Europe, etc.). Dedicated regular discussion fora with authorities, which may include also related industries (aviation, defence, electronics, etc.) should be considered. As shown, a strong argument for authorisation for space applications is often not sufficient to secure the continued use, as authorisation fundamentally challenges the continuation of supply. This raises the general question of appropriateness of authorisation for broadly used SVHC substances.

The current lists (CoRAP, PACT/RMOA, Candidate List, Annex XIV, etc.) have to be tracked manually by the user.



## REFERENCES

 COM(2016) 705 "Space Strategy for Europe" – Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions (26 October 2016), available at

http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item\_id=8975&lang=en\_

- <u>Parliamentary question (E-003827-2016) "Impact of REACH legislation on the European space industry"</u> (9 May 2016) and <u>Answer given by Ms Bieńkowska on behalf of the Commission</u> (28 July 2016)
- <u>Space Chromates Task Force ('STF') Comments on the CTAC(Sub) application for authorisation in public</u> <u>consultation</u> (6 October 2015)
- ASD-Eurospace response to the EC public consultation on REACH Authorisation (29 April 2016), available at <a href="http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item\_id=8081">http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item\_id=8081</a>
- ESA, REACH Obsolescence Risk Management for Space Programs (22 April 2015)
- <u>1st Space Stakeholders' Day on REACH</u> Summary and presentations (2 December 2013)
- COM(2013) 108 final "EU Space Industrial Policy" Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions (28 February 2013), available at

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0108

• ASD-Eurospace Position Paper on hydrazine (14 June 2012)



# ANNEX: REACH STATUS OF GOVERNMENTAL AGENCIES

There is remaining uncertainty whether a non-industrial actor and governmental agency such as national space agencies as well as ESA may have obligations under REACH due to the fulfilment of related REACH roles as:

- "downstream user" (Article 3(13)) when using substances in the course of its activities;
- "supplier of an article" (Article 3(33)), e.g. in case of the procurement of payload from outside EU and its further provision to the industrial system integrator (raising the question about the applicability of REACH Article 33).

In relation to ESA the ESA Convention<sup>27</sup> states that the Agency shall have legal personality (Article XV (1), Annex I<sup>28</sup> Article I). On the other hand the REACH Regulation states in its Recital 16: *"This Regulation is based on the principle that industry should manufacture, import or use substances or place them on the market with such responsibility and care as may be required to ensure that, under reasonably foreseeable conditions, human health and the environment are not adversely affected."* Also, *"consumers"* (which are not further defined in the REACH legal text) do not have REACH obligations.

A status clarification with the support of the European Commission legal services is recommended.

<sup>&</sup>lt;sup>27</sup> http://download.esa.int/docs/LEX-L/ESA-Convention/20101200-SP-1317-EN\_Extract\_ESA-Convention.pdf.

<sup>&</sup>lt;sup>47</sup> Annex I also foresees certain Privileges and Immunities, e.g. for goods imported or exported by ESA, see Article VI.